

# **Common Reprocessed SUDs and Problems with Reprocessing**

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# **Regulation Of Reuse Of Single Use Devices**

- **The OST Research Team decided to examine some of the issues that might be important in the reuse of single use devices (SUDs).**
- **We collected SUDs being discarded by Walter Reed Army Hospital and Washington Hospital.**

# **FDA/CDRH/OST Research Team**

- **Katharine Merritt**
- **Stanley Brown**
- **Vicki Hitchins**
- **Terry Woods**
- **Scott McNamee**
- **Anne Lucas**

# **Issues To Be Considered**

- **Problems with cleaning**
- **Problems with sterilization**
- **Problems with performance**



# **Cleaning Issues**

- **If you can't/don't clean the device, you can't adequately disinfect or sterilize it.**
- **If you can't disinfect or sterilize it adequately, it can't be reused and performance isn't an issue.**
- **Devices must be dry before gas sterilization is effective.**

# Initial Findings

- Many of SUD's go over guide wires to aid insertion.
- These guide wires track debris into the lumen which must be cleaned for reuse.
- There may be other open lumens that need to be cleaned.
- Some lumens are not readily apparent.
- Balloon lumens are closed and hard to clean.

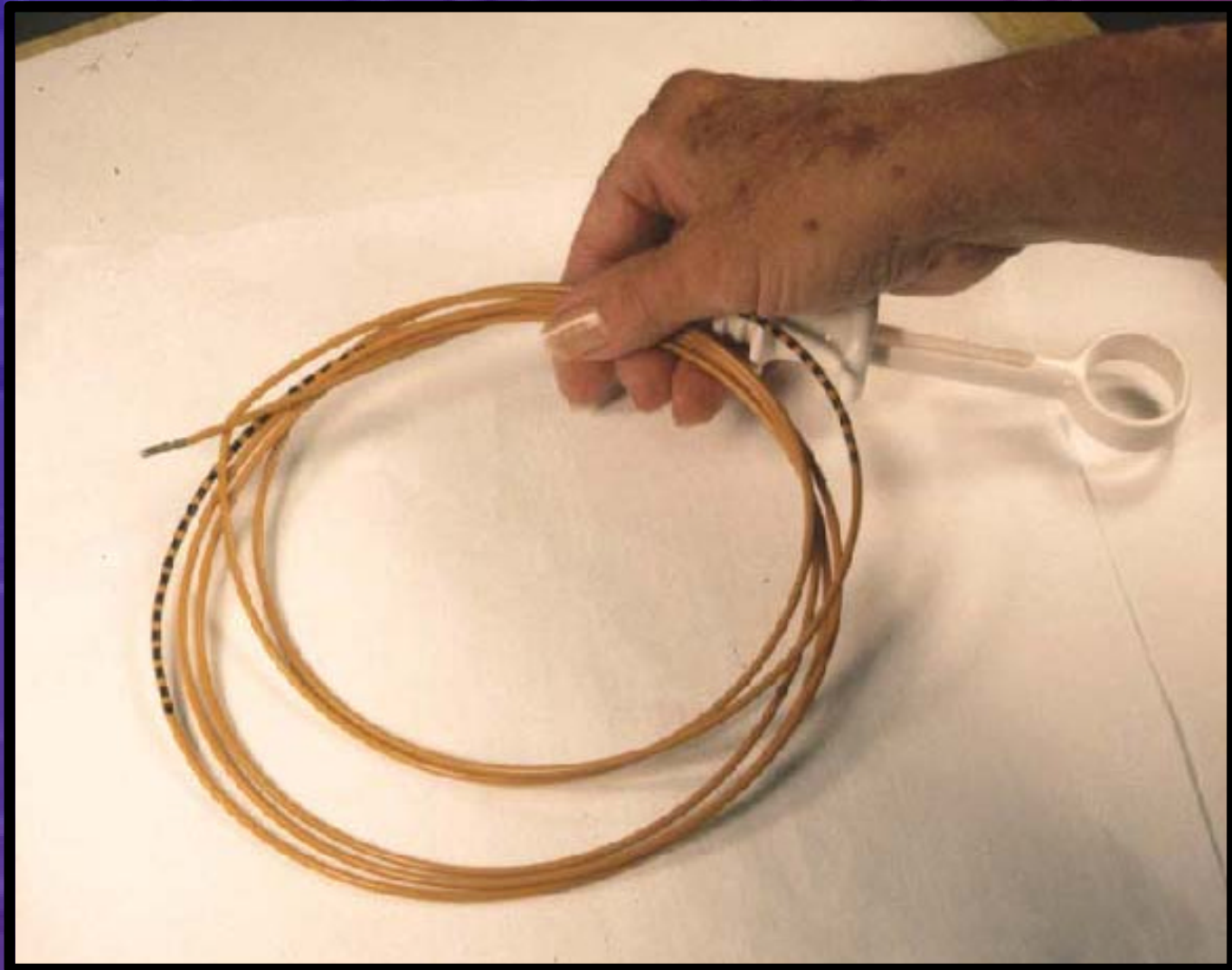
# **Purpose of This Presentation**

- **To show some of devices examined and the problems found**
- **Tips on what to look for**
- **Protocols addressing problems need to be established and followed**

# Examples of Some GI Devices

- Are among those SUDs being reprocessed for additional use
- Are very simple devices and appear robust and easy to clean
  - However there were some surprises in the results

# GI Biopsy Forceps--- About 9 Feet Long



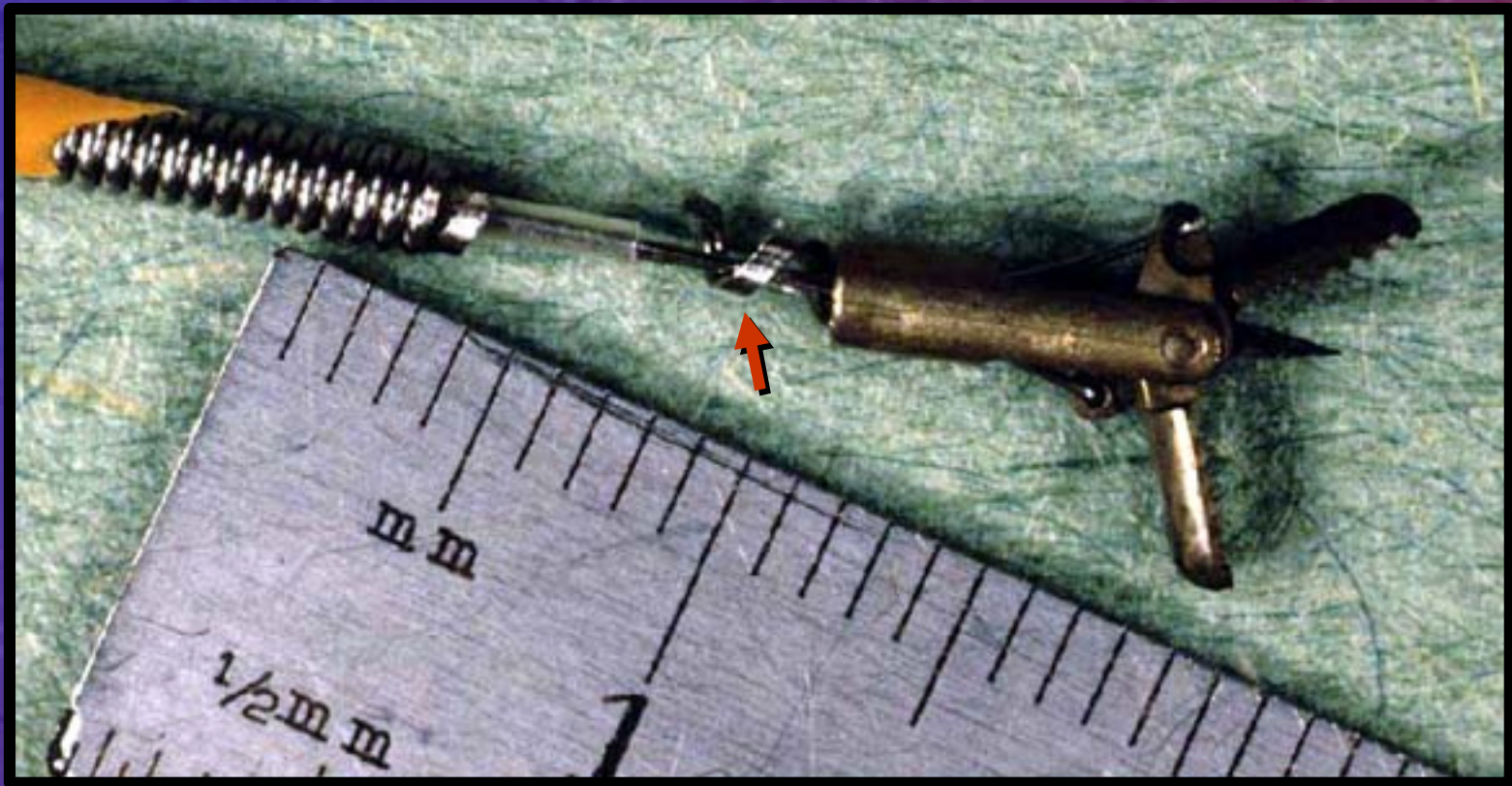


# The Handle Operates the Jaws

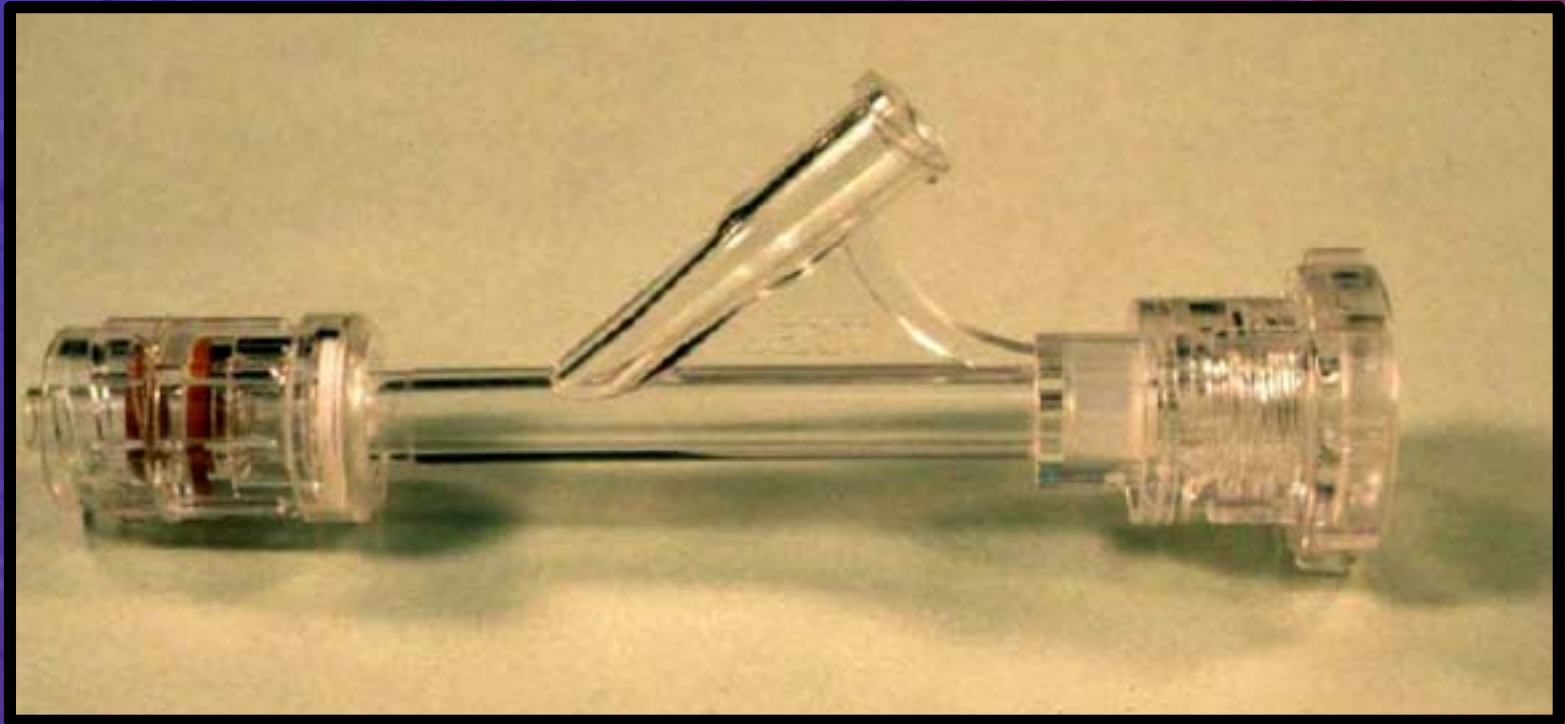




**This Shows the Jaws, the  
Cabling and the Lumens**

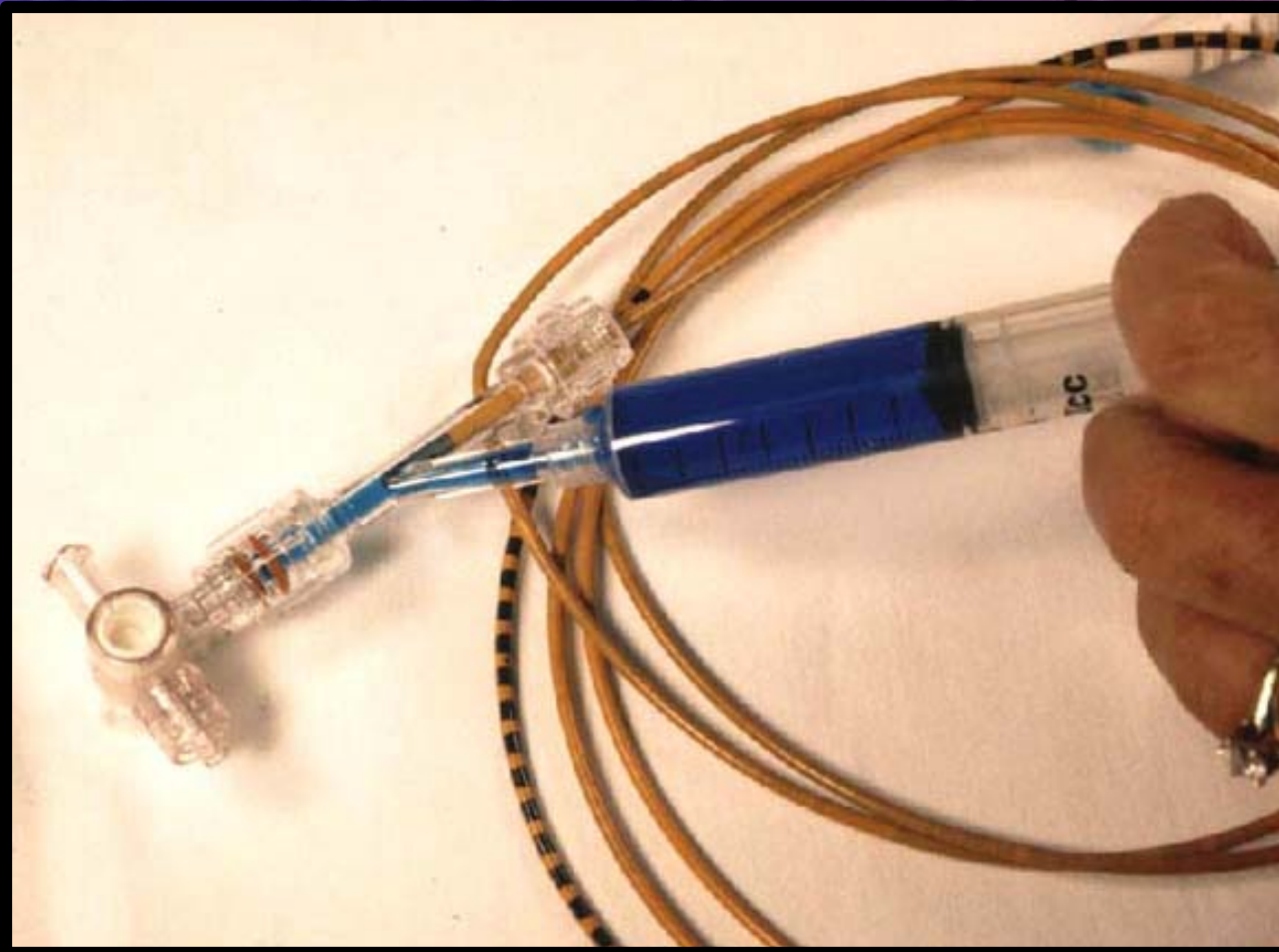


**A Tuohy Was Used to Test for an Open Lumen. It Has Also Been a Good Device to Help Clean Lumens.**

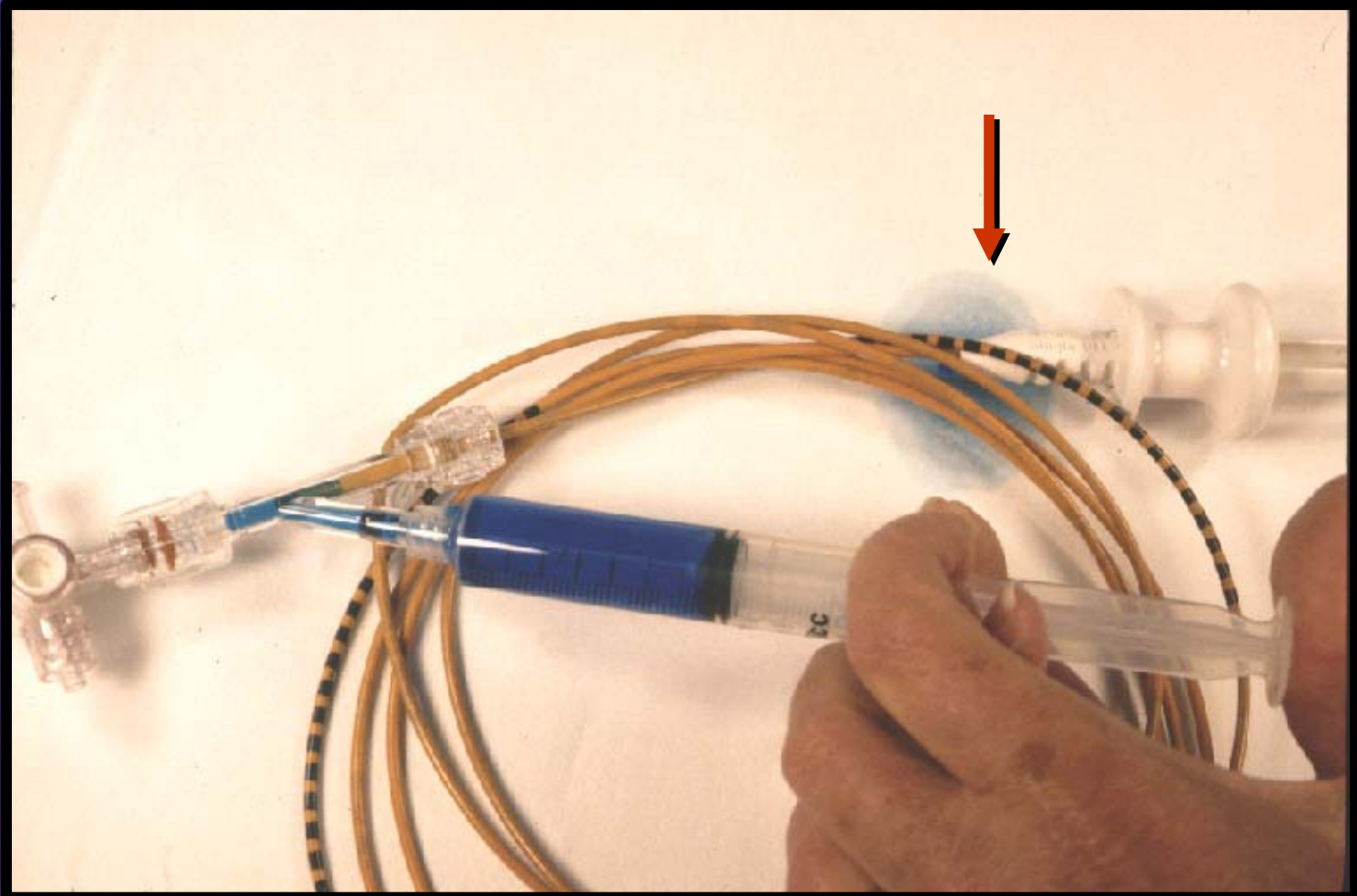




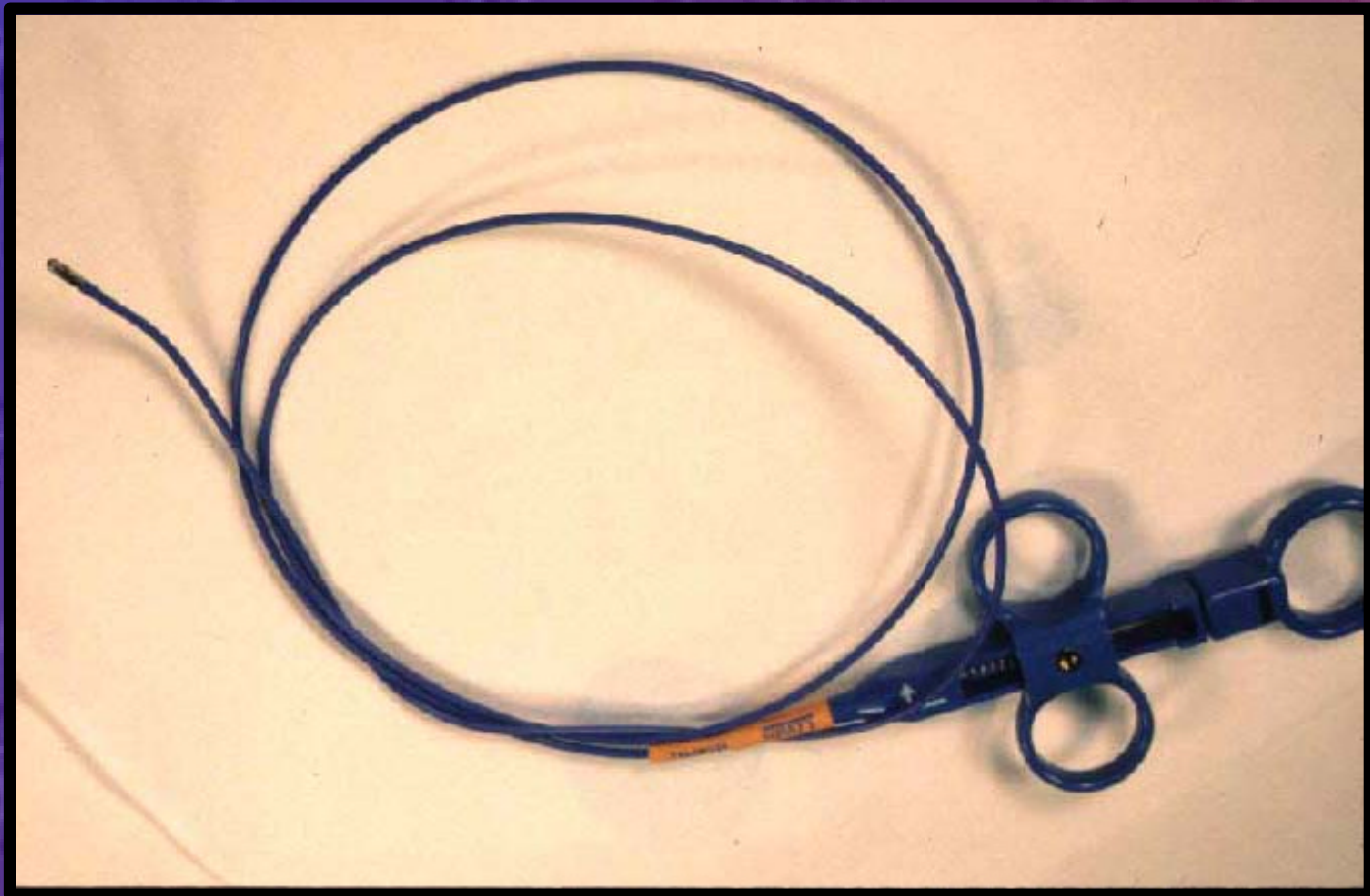
# **Dye Was Back Flushed Through the Jaw End of the Forceps**



# Dye Emerged at the Junction With the Handle



# Cardiac Biopsy Forceps Have the Same Issues As GI Forceps





# Red Dye Emerged at the Handle Junction



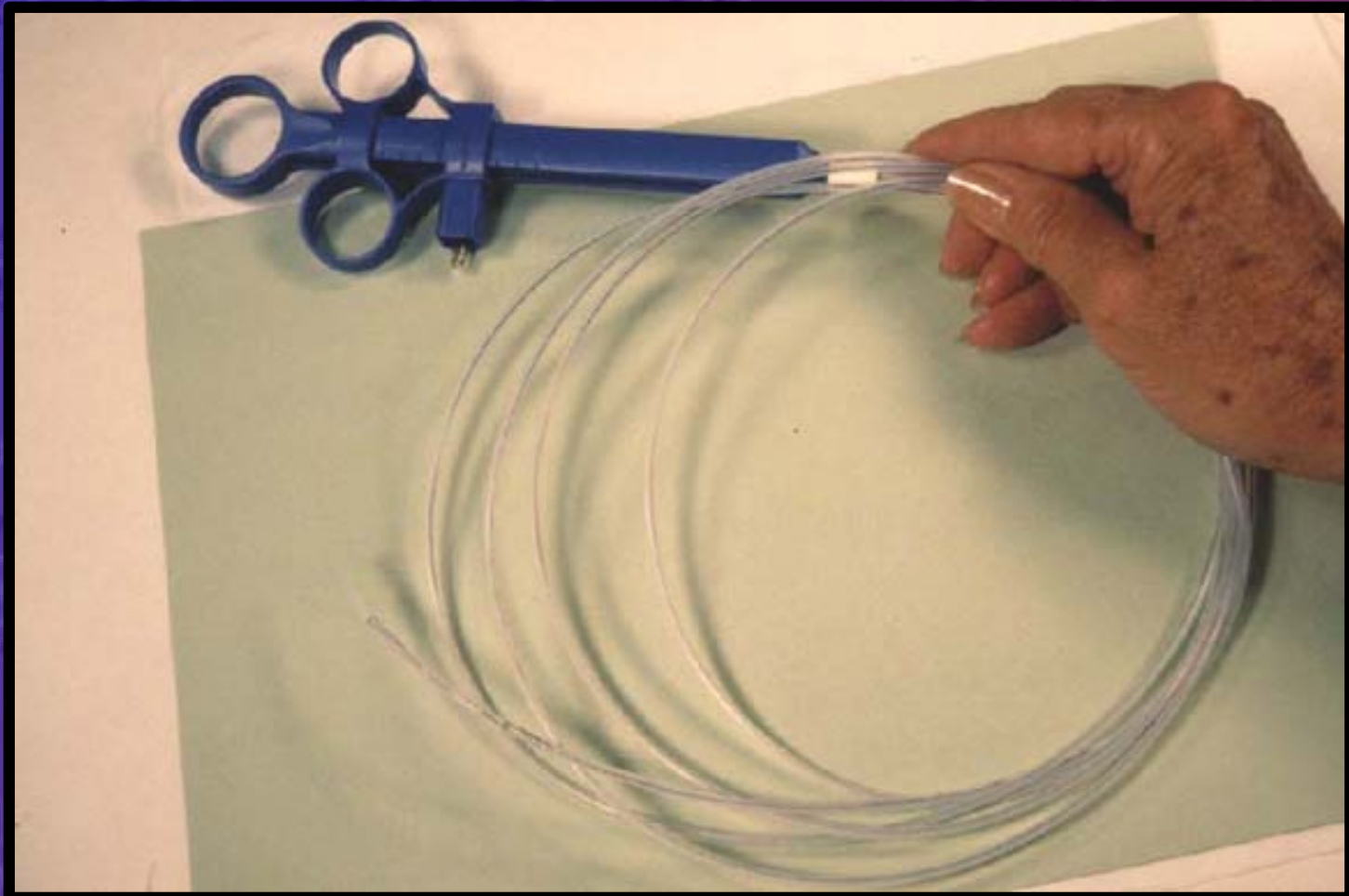


**Shows the Pool of Red Dye Under the Handle**



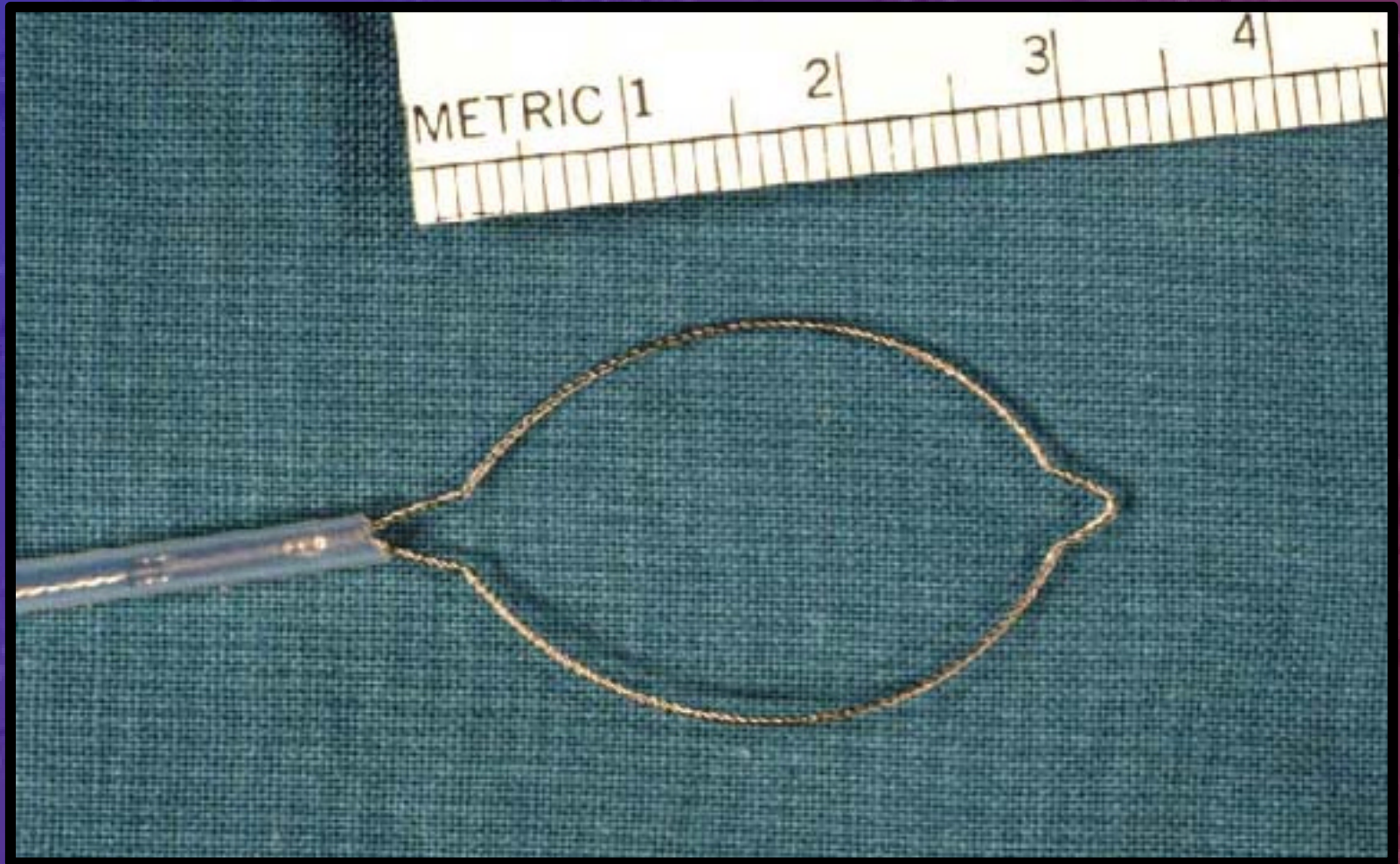
- **Biopsy forceps (there are many kinds) have an open lumen that can trap patient material.**
- **Lumens must be cleaned for the device to be safe.**
- **Lumens may go unrecognized.**

# GI Snare With Transparent Tubing Are About 9 Feet Long

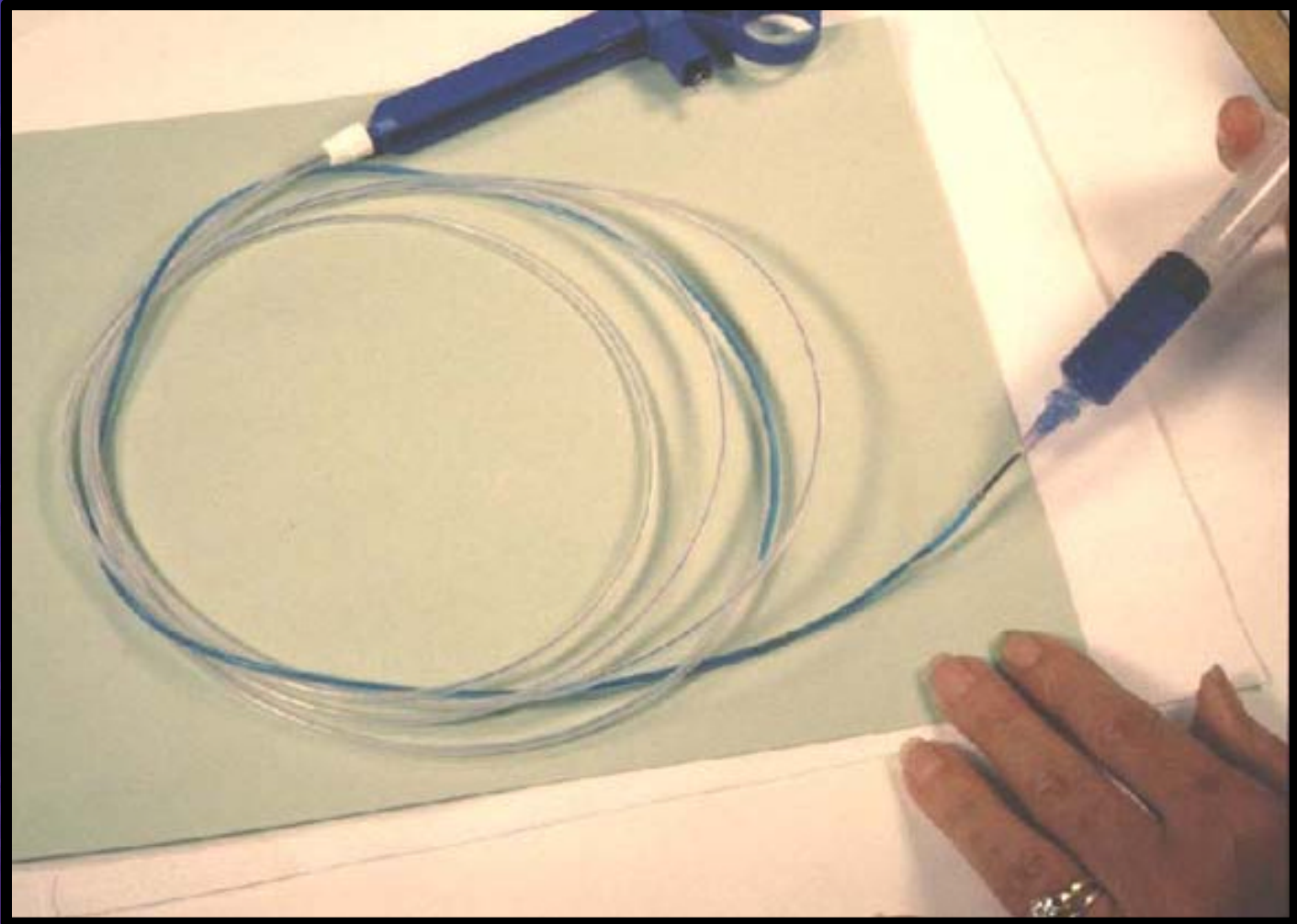




# Handle Operates the Snare

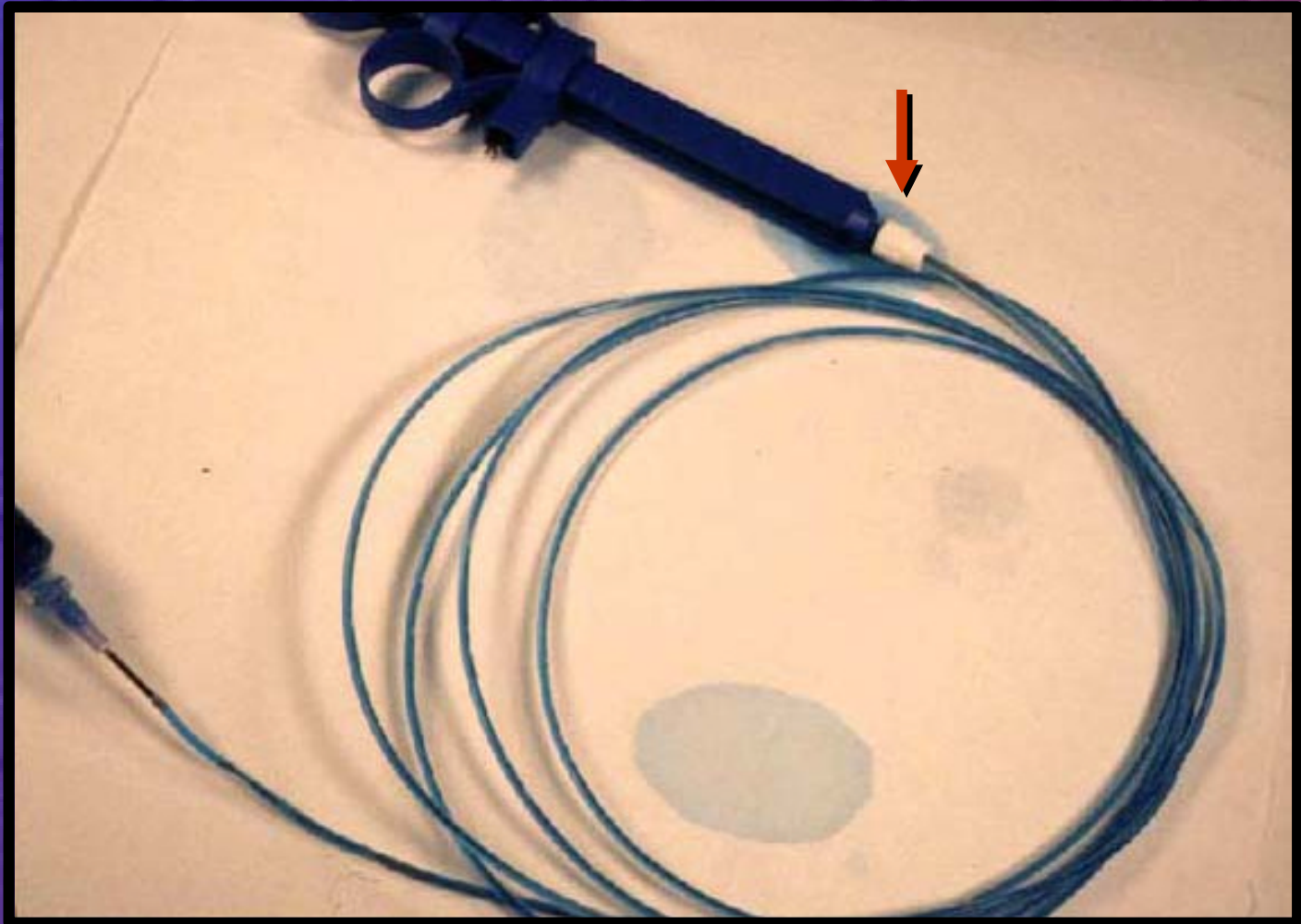


# Dye Can Be Inserted Using a Syringe and Needle



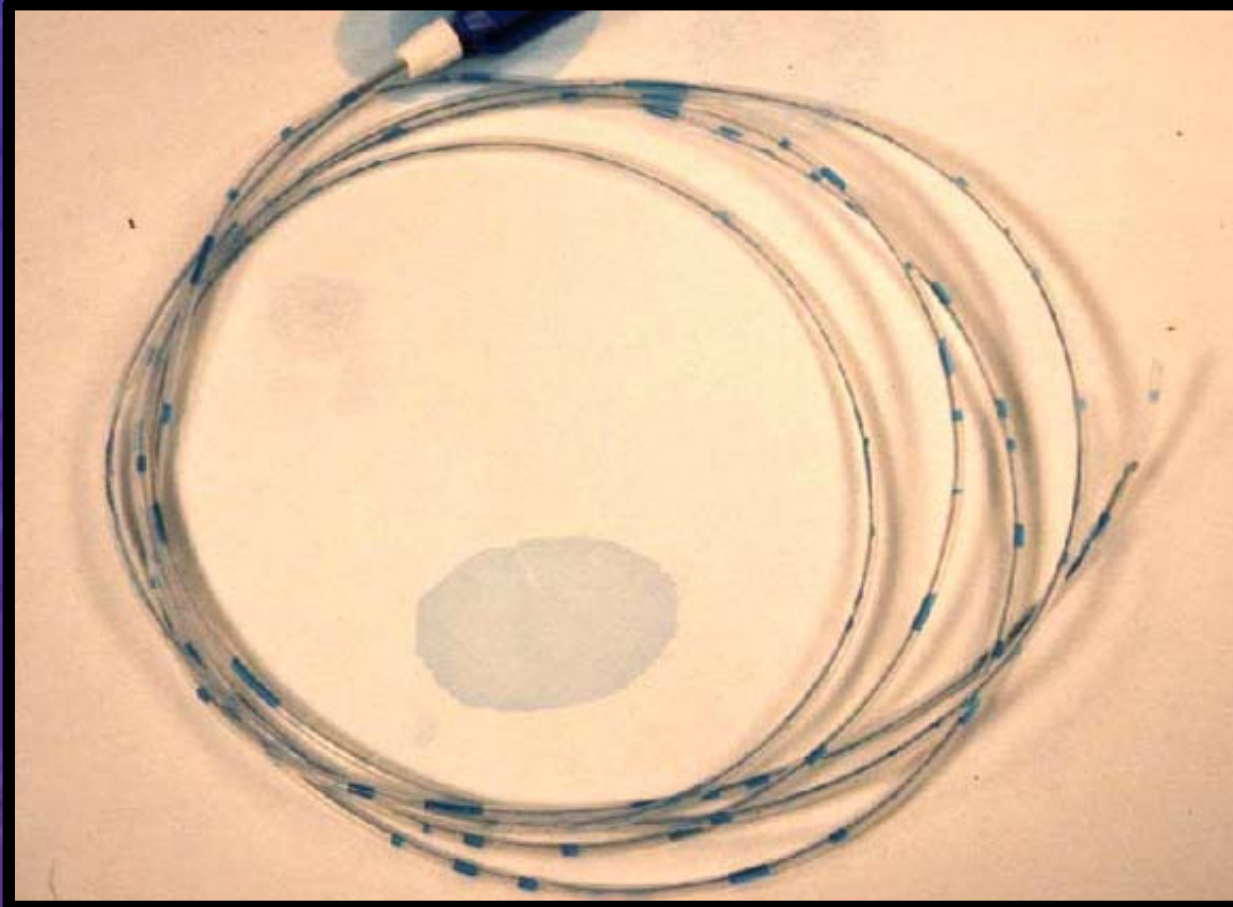


# Dye Comes Out at Handle End





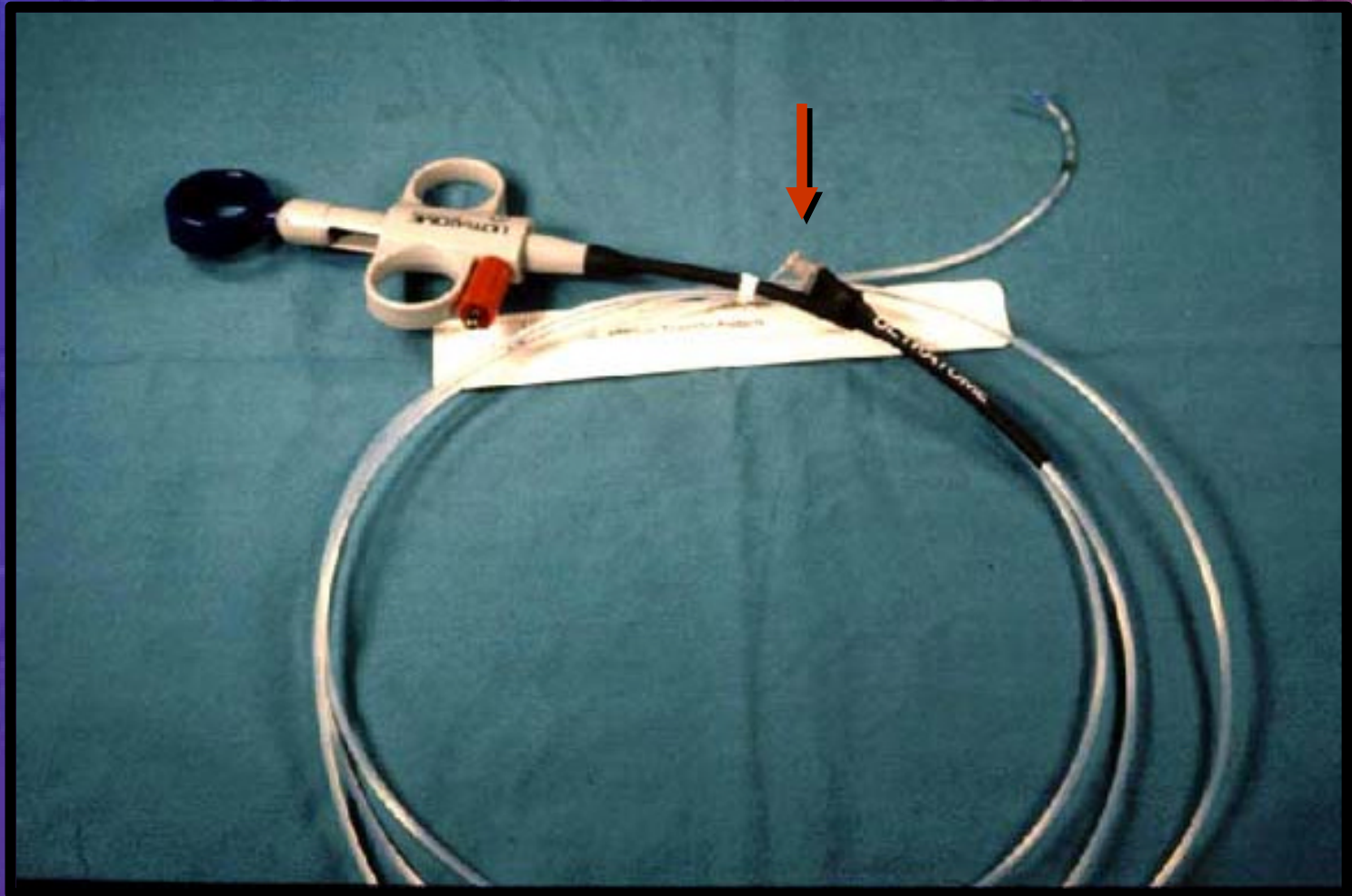
# **When Dye Is Withdrawn, Droplets Show the Hydrophobic Nature of the Tubing**



**Difficult to Clean and Dry**

- **Biopsy forceps have unrecognized open lumens.**
- **Devices with transparent tubings have obvious lumens and trapped debris.**
  - **Lumens are difficult to clean and dry.**

# ERCP Device Commonly Reprocessed Is Long



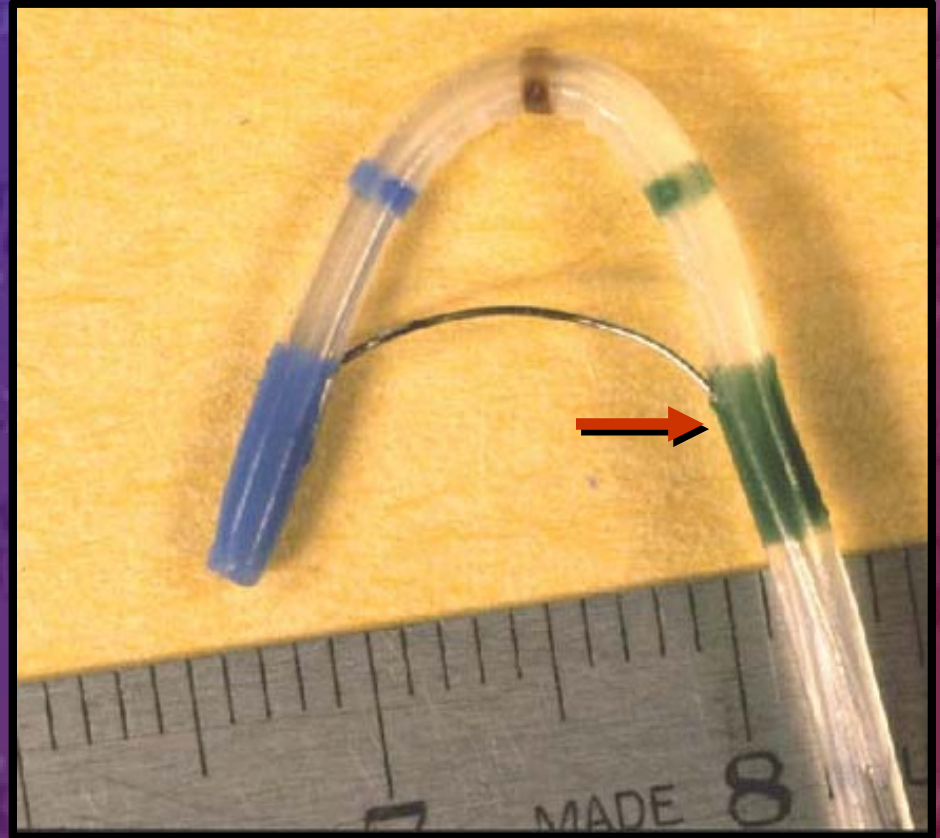
Guide Wire Lumen Can Be Flushed With a Syringe



**Handle Operates the  
Wire Which Bends  
the Tubing.**

**Allows Trapping the  
Tissue or Stone for  
Removal.**

**Patient Debris Gets  
Trapped in the Wire  
Channels.**



# **Guide Wire Lumens**

- **Many cardiovascular devices use guide wires that have been inserted to reach the correct location.**
- **Wires track blood into the lumens.**
- **Lumens must be identified and cleaned.**

# PTCA Devices

- Are about 5-6 feet long and very narrow.
- Come in many types and forms.
- Some are used to deploy stents.
- Some are used just to open the vessel.
- Some have guide wire lumens that:
  - are open and easy to clean.
  - are hard to clean.



# Balloon Channels

- The PTCA's have collapsed balloons for a narrow profile for entry into the vessel.
- Balloons are expanded to deploy stent or clear clogged vessel.
- Radiopaque dye is used to visualize balloon expansion.
- Dye must be removed from balloon channel.
- Balloon channel is a closed lumen.

**Upper Manifold Provides Access for  
Cleaning Guide Wire Lumen.  
Bottom Is for Balloon Channel.**

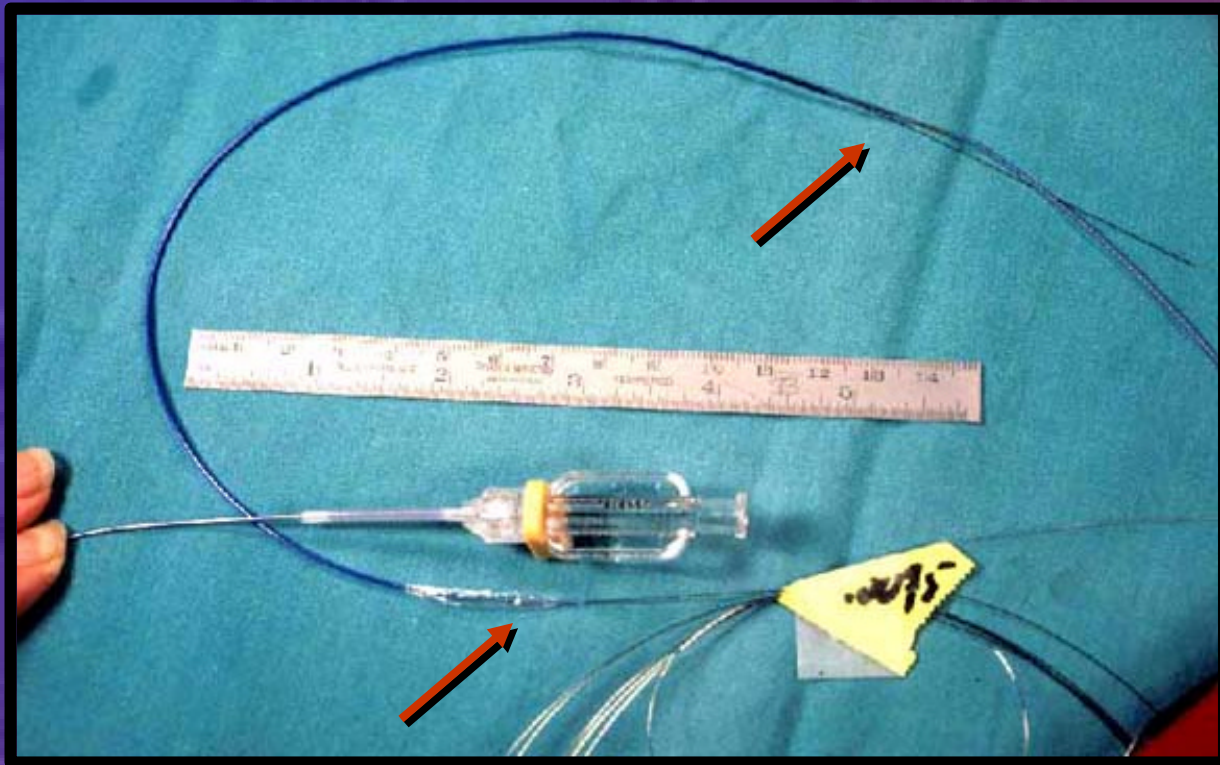


**This PTCA Has 3 Lumens Which  
Must Be Cleaned, Two Are Open  
And One Is the Balloon Channel.**





**Side Rail or Quick Exchange PTCA Has a  
Manifold for Only the Balloon Channel,  
but It Has a Guide Wire Lumen.**



**Guide Wire Enters at Balloon End  
and Exits Further Up**



**Back Flush With a 27 Gauge Needle and Syringe.  
This Poses Numerous Hazards.**



**Some Quick Exchange Catheters Have Vent  
Holes Which Trap Debris.  
Note the Crystals in the Balloon.**

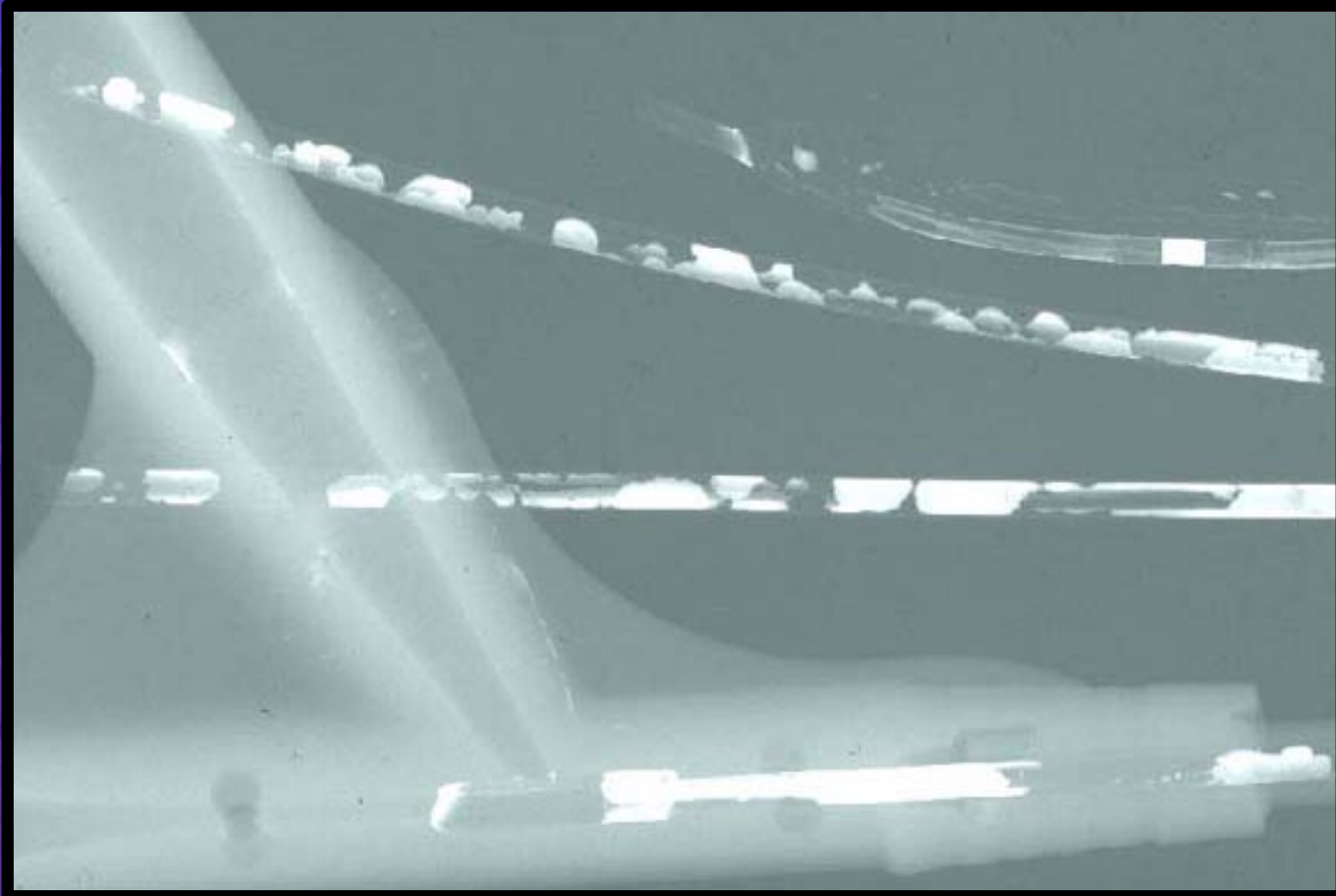




**Balloon Channels, Which Are a Closed Lumen, Must Be Cleaned. Crystals Will Interfere With Balloon Function. Some Types Were More Difficult to Clean Than Others.**

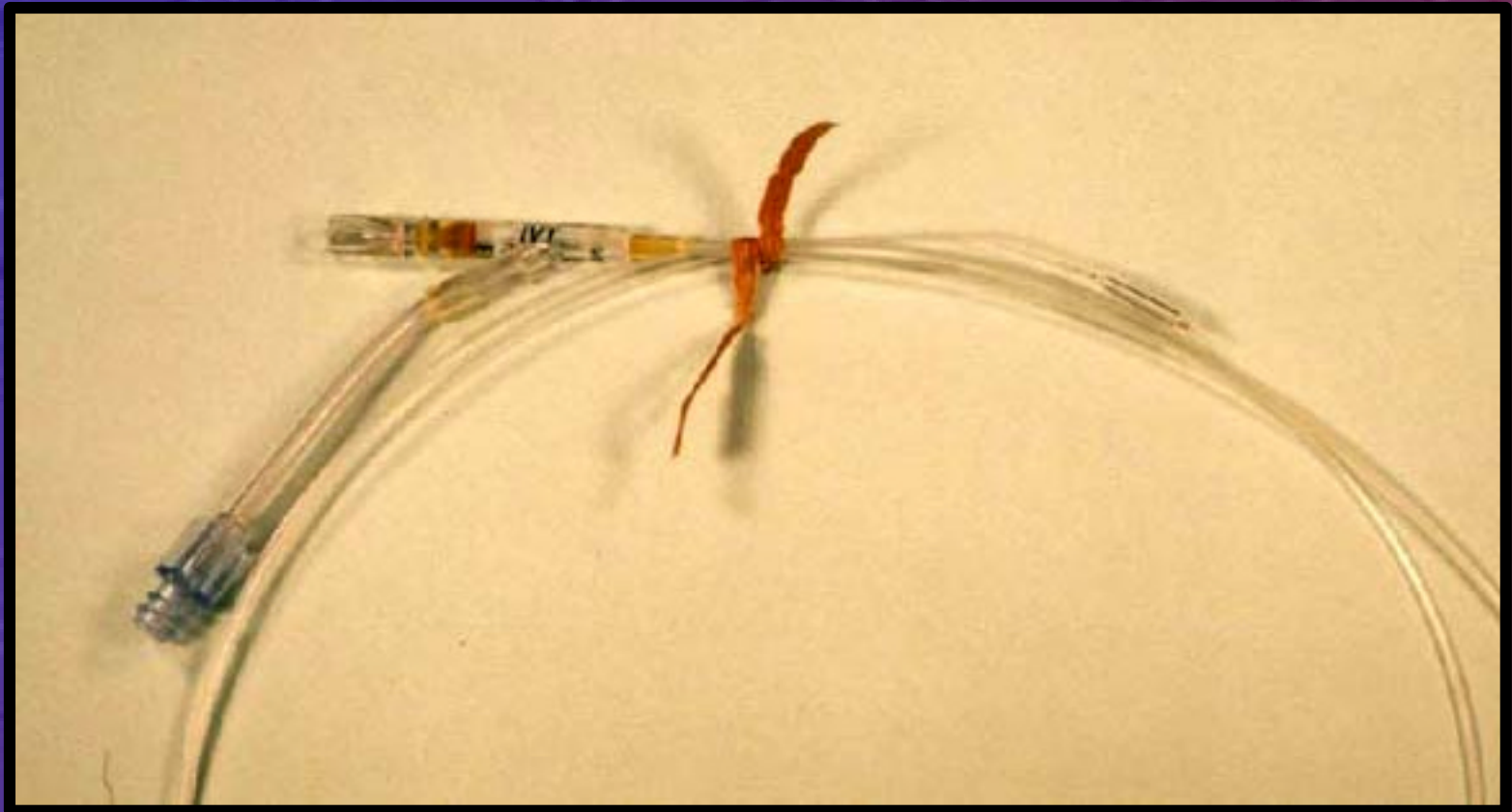


**X-ray of a PTCA Thought to Be Cleaned of  
All the Dye.  
Note the Accumulations.**





**PTCA Used to Scrape the Clot or Plaque.  
It Has an Open Guide Wire Channel.**



**Red Dye Was  
Used to Expand  
and Visualize  
Balloon and  
Razor Edges**



**Close up of Razor Edges Using Air to  
Expand Them.  
They Are Sharp and Hard to Clean.**

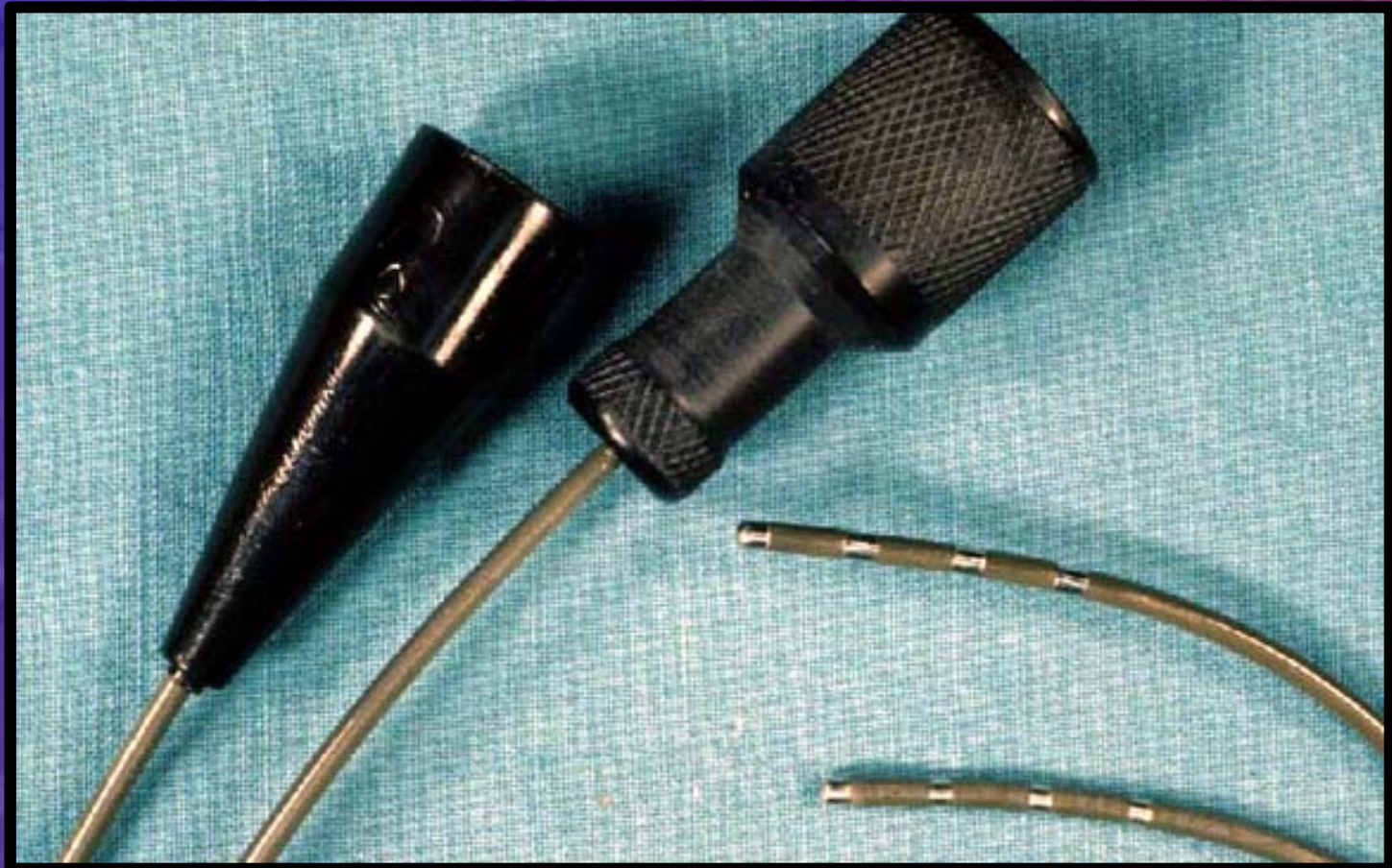


# **Electrophysiology Catheters (EP's and Ablators)**

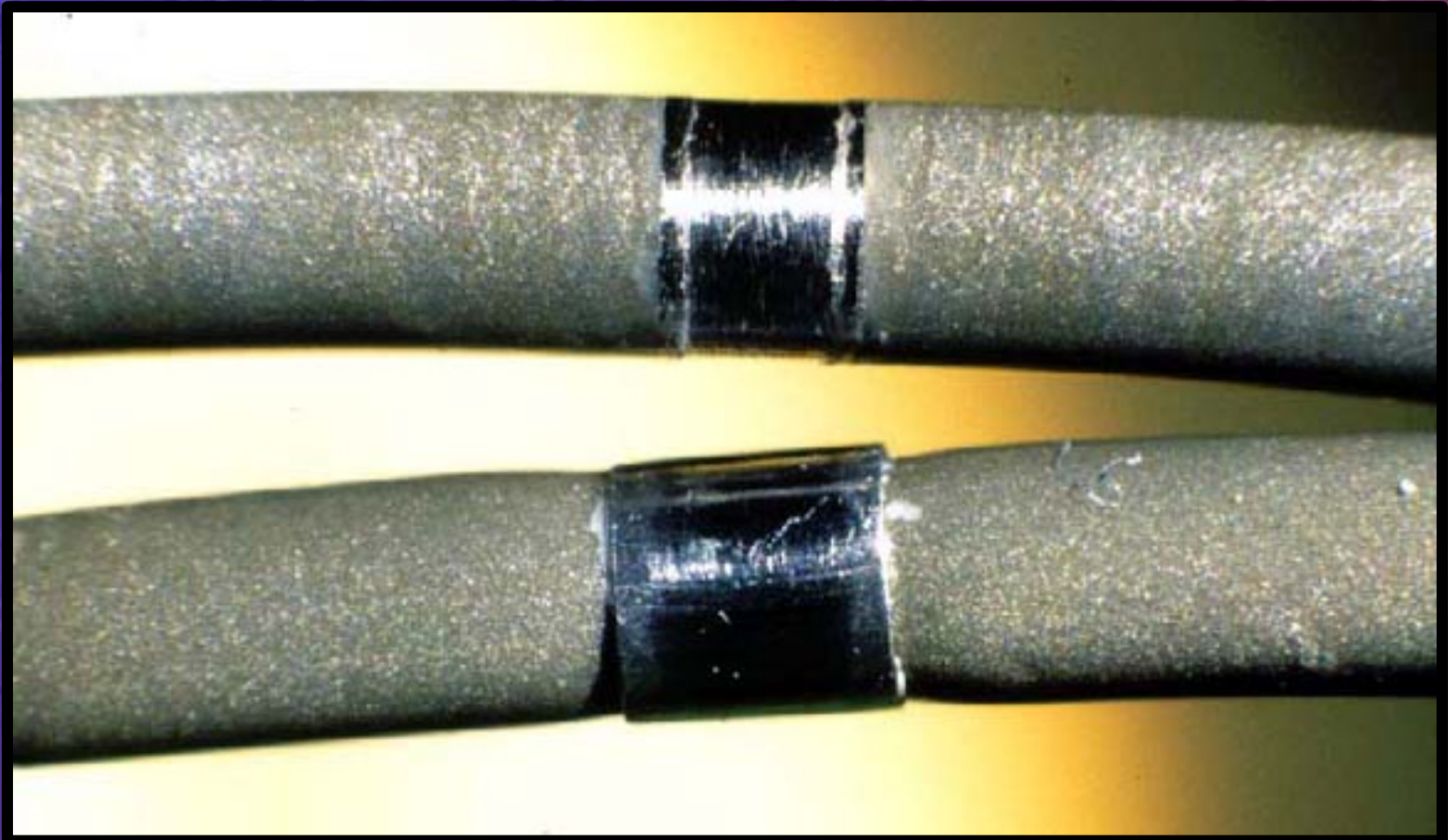
- **Solid devices with electrodes to map electrical activity of the heart**
- **Ablators deliver an electric pulse**
- **Ablators have a thermistor in the tip**
- **Must be carefully cleaned**



**Ep's Seemed Robust and Easy to Clean,  
but There Were Two Different Types of  
Connectors.**



**Closer Examination Revealed There Were Differences in the Way the Electrodes Were Sealed to the Shaft.**





**Further Study Using  
Air, Demonstrated  
That the Crimped  
Electrodes  
Were in Fact an Open  
Lumen**

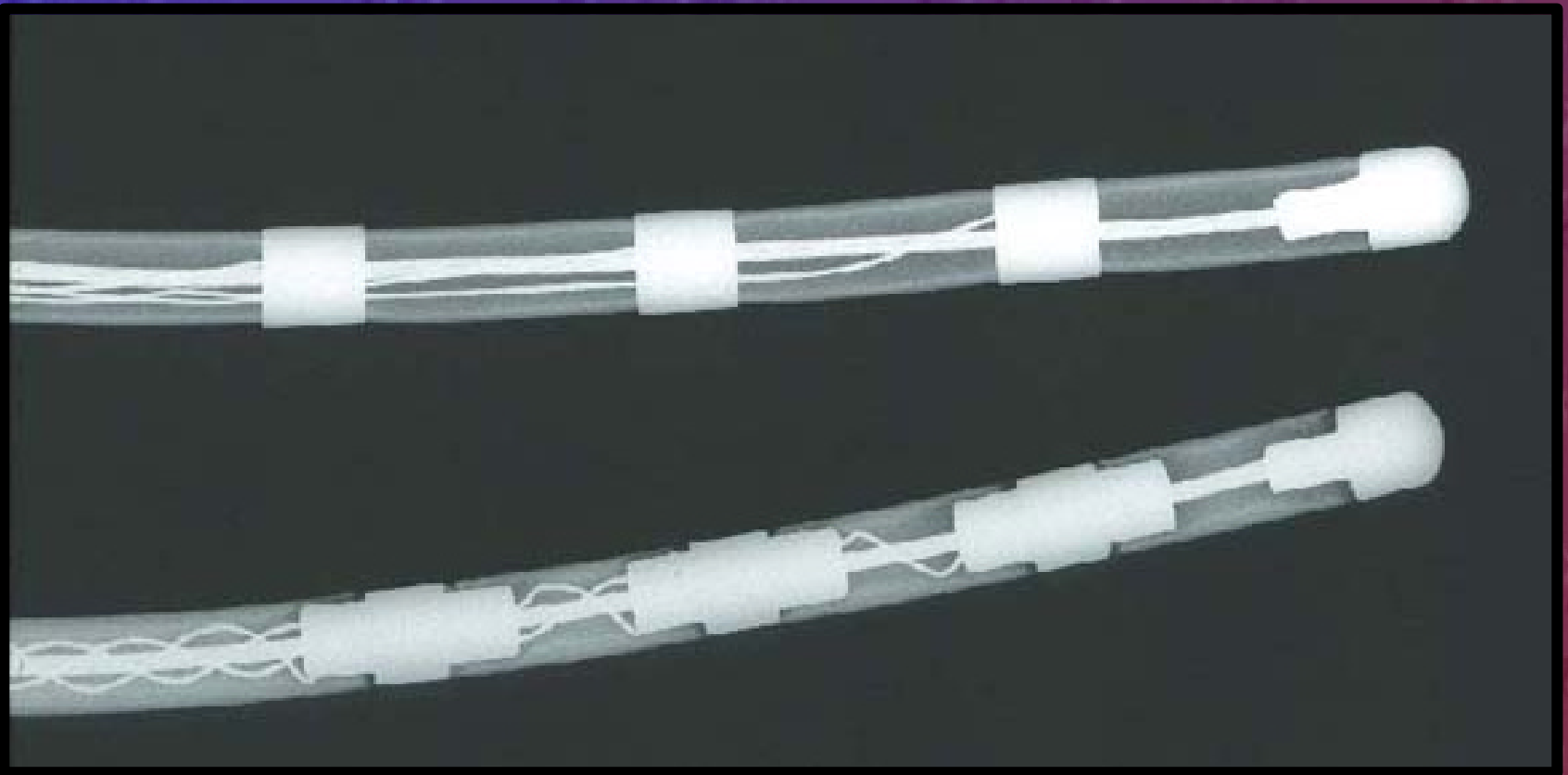


**Examination of  
the Shaft  
Revealed That  
One Was Molded  
and  
The Other Had an  
Open Channel**

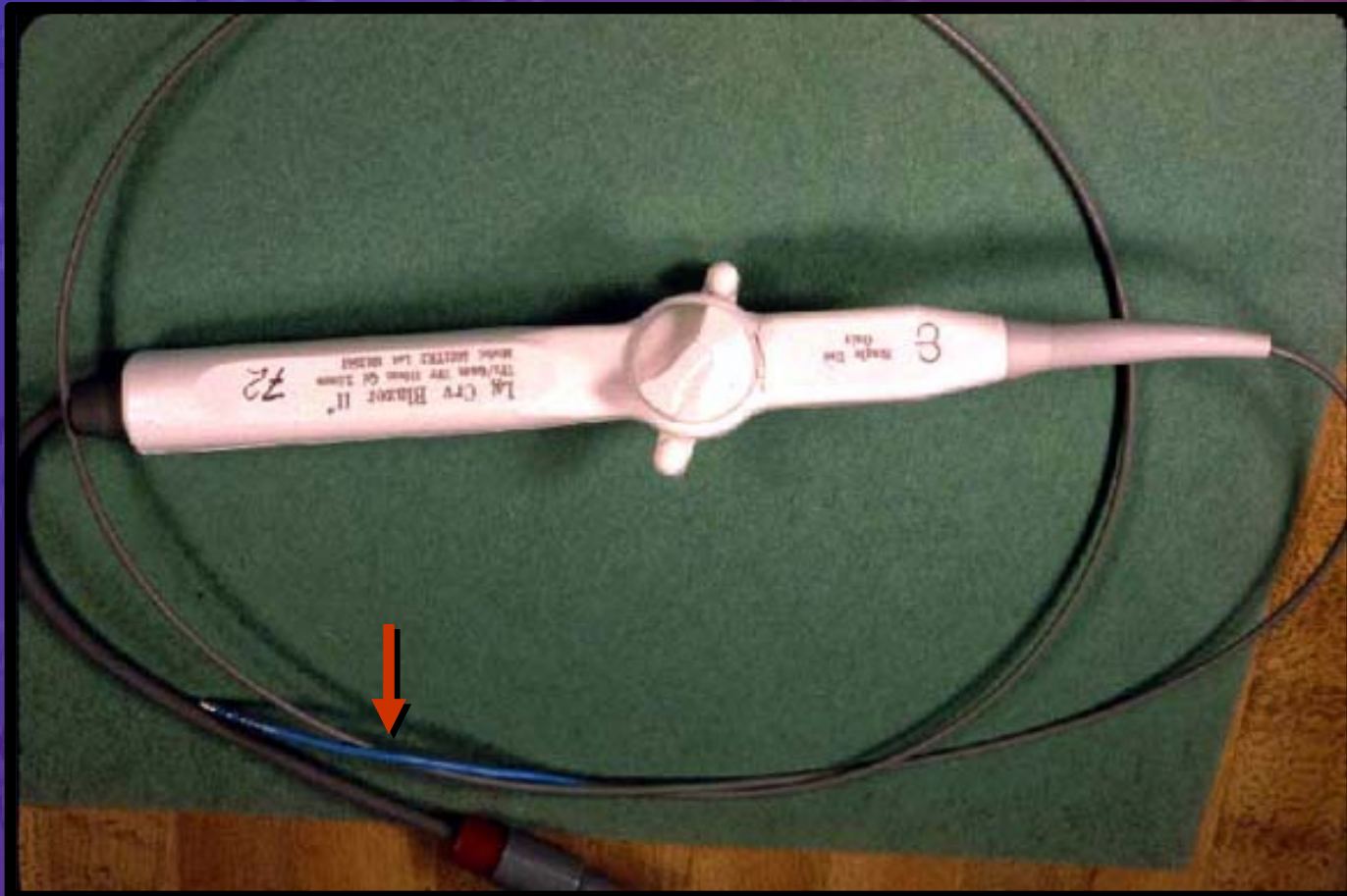




# **X-ray of Two Shafts Shows a Major Difference**



**Common Type of Cardiac Ablator.  
Handle Steers Electrode (Blue at Bottom)  
to the Site.**



# Electrode Band and Tip of the Ablator





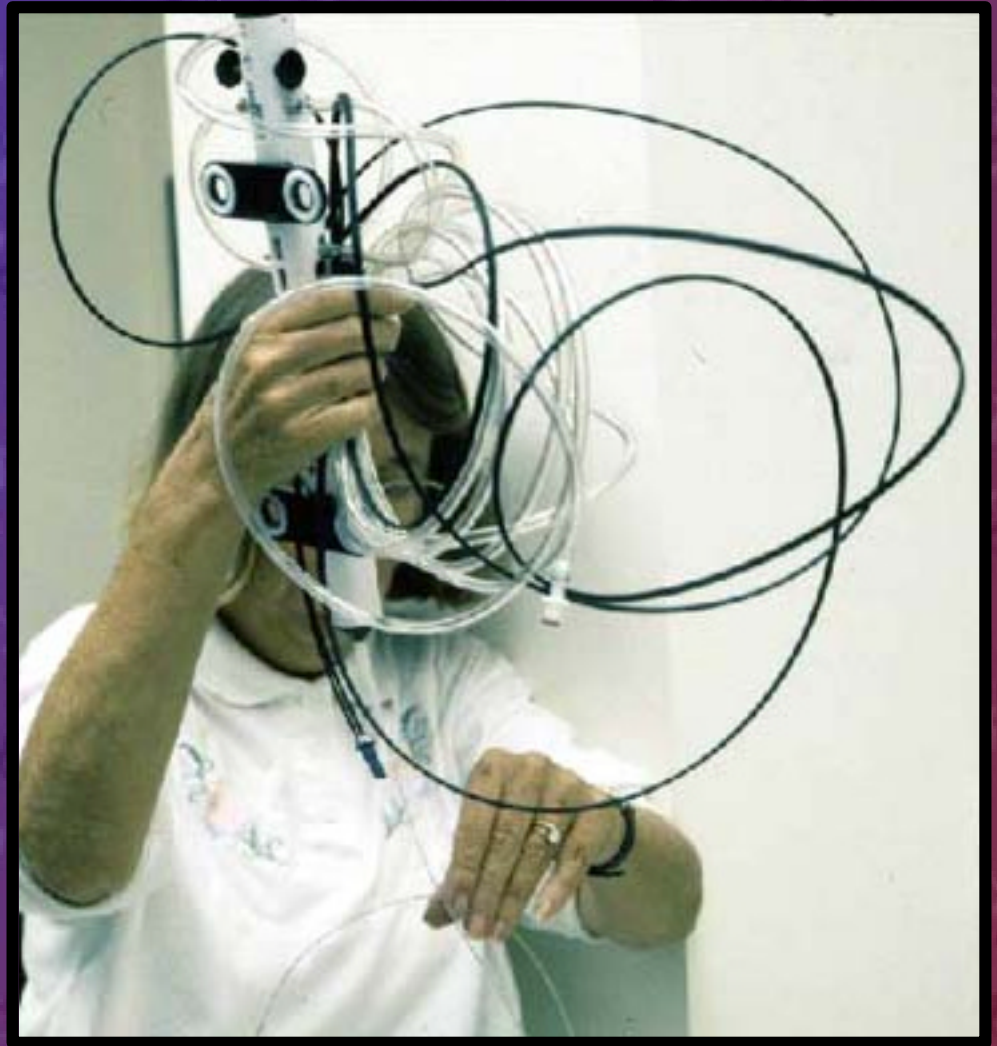
# Seal on an Electrode Leaked With Fluid Trapped Beneath It.



# **Other Cardiac Devices**

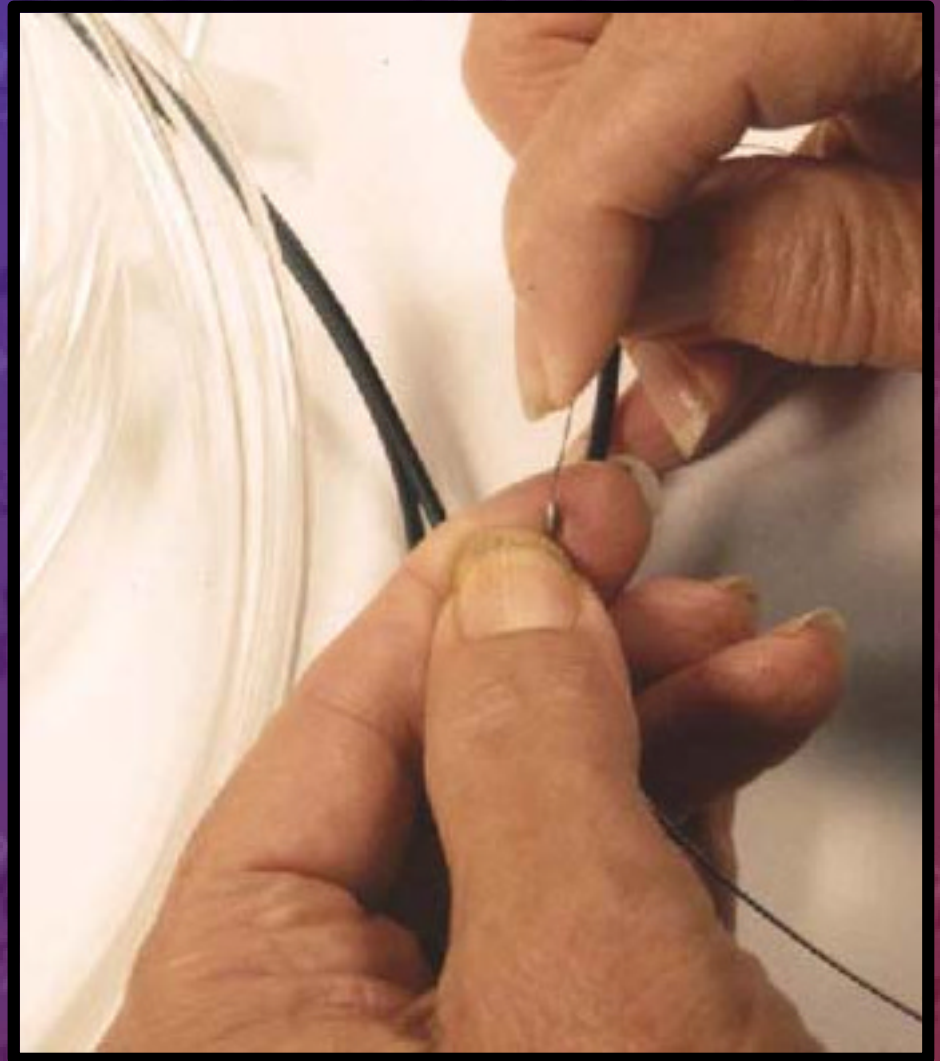
- **Devices to remove clots and blockage**
- **Devices to visualize the site**
  - **Most go over guide wires and guide wire channel must be cleaned**

**Rotoblator Is  
Driven by  
Nitrogen or Air  
To Break Through  
the Clot**

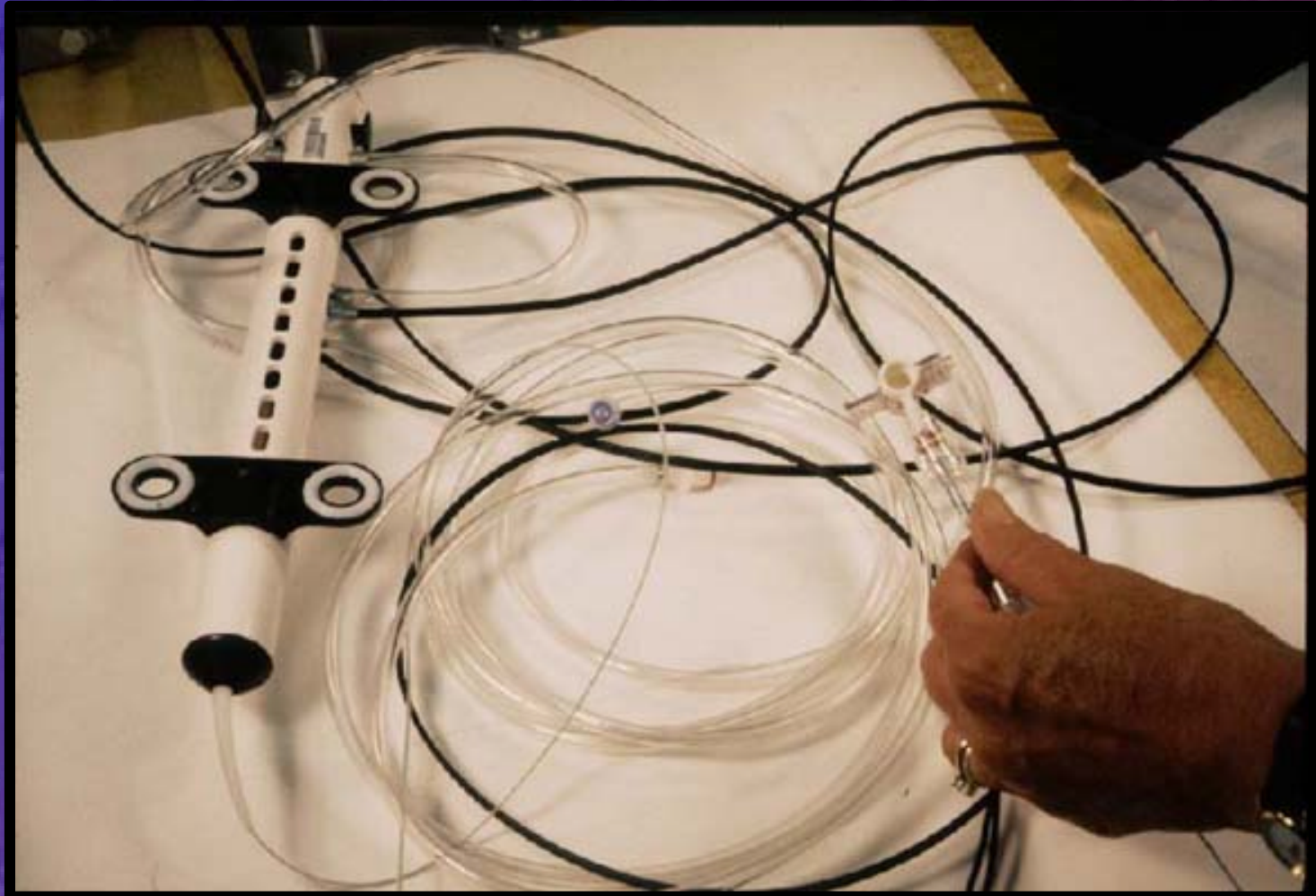




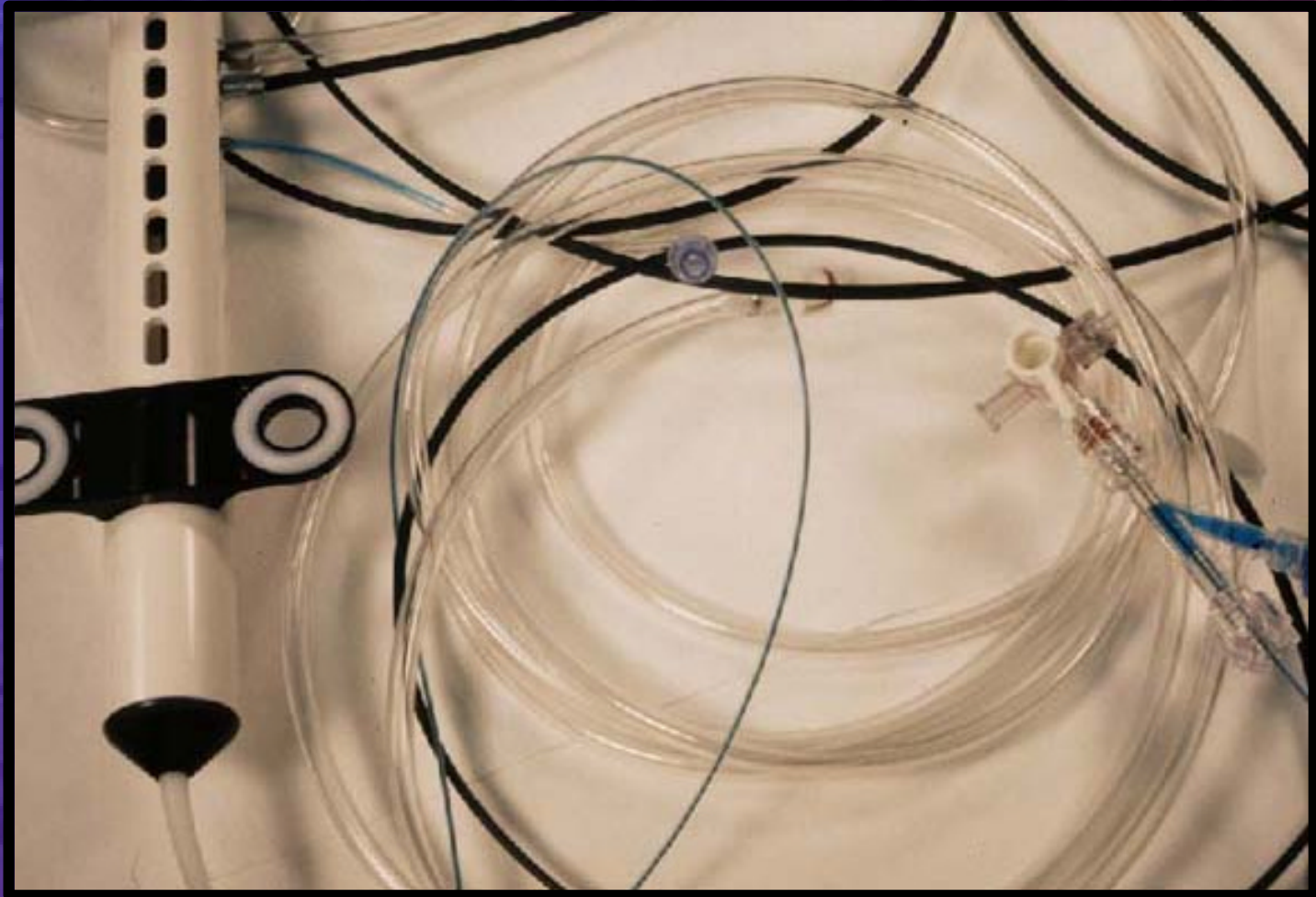
**The Very Narrow  
Guide Wire  
Channel Which Is  
Too Small to Use a  
Syringe and  
Needle to Clean.  
Only the Smallest  
Guide Wires Will  
Enter It.**



**It Has Many Pieces of Tubing and Not All the Sites That Would Contact Blood Are Easy to Identify**

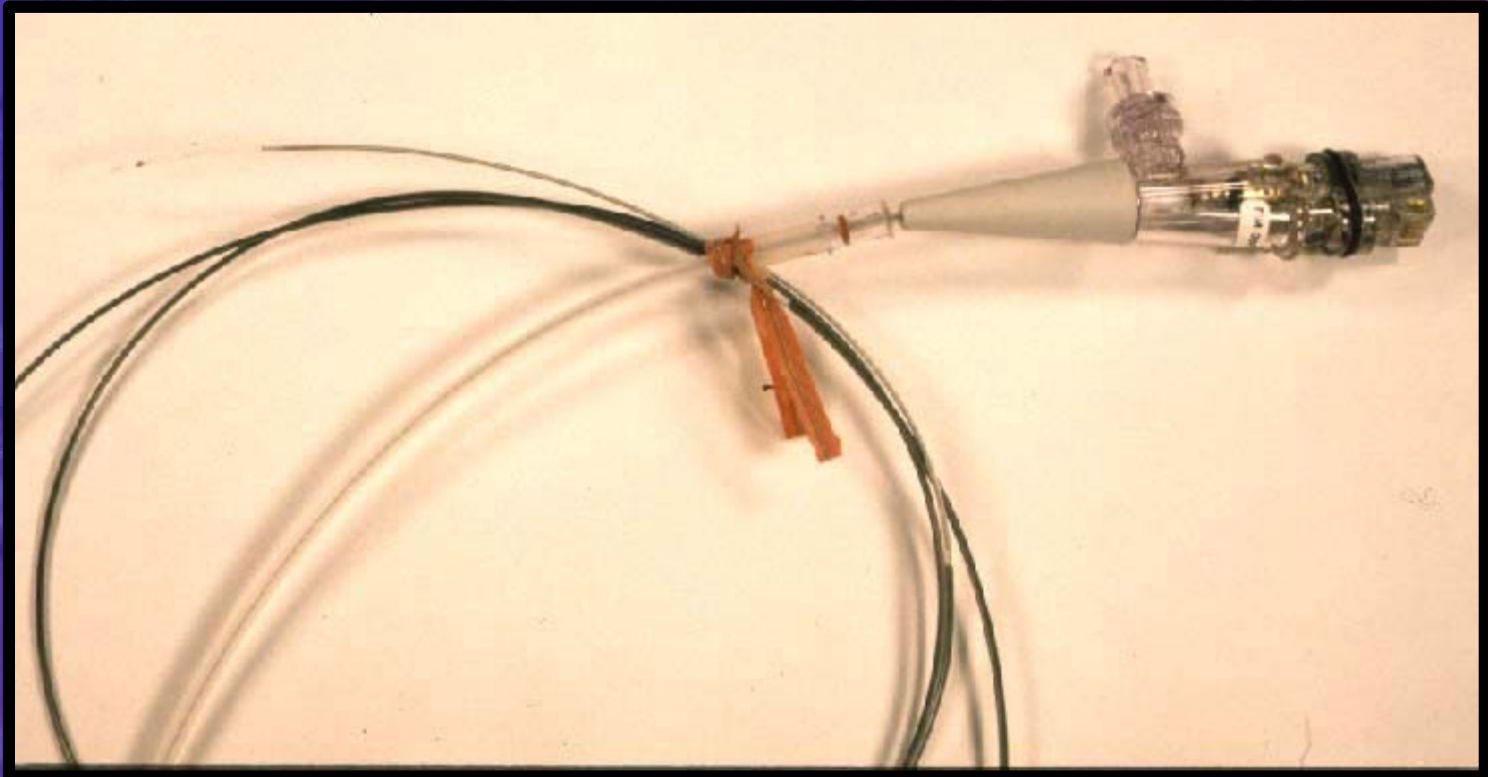


# **The Use of the Tuohy and Dye Demonstrates One of the Blood Contact Sites.**

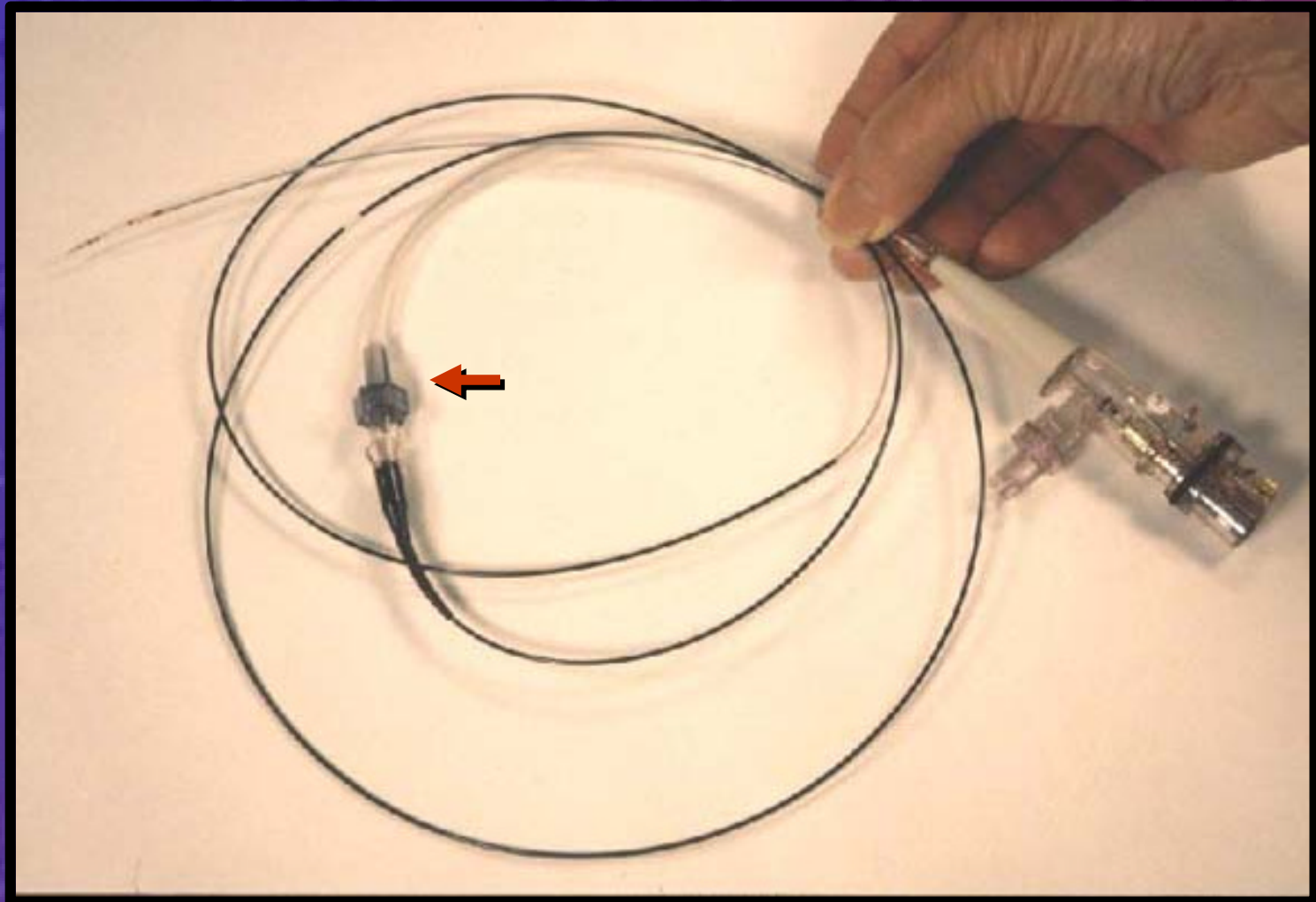




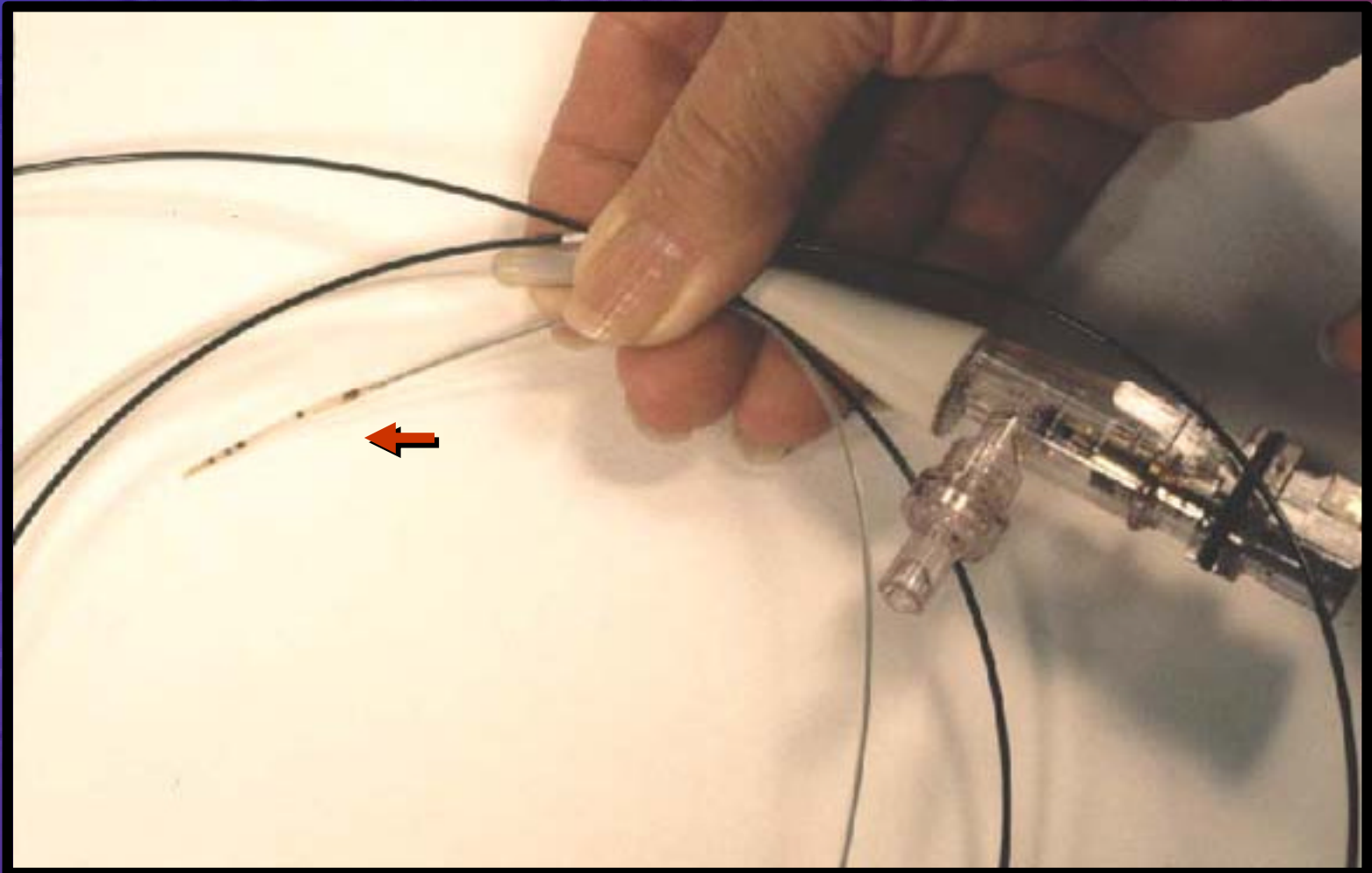
**Ultrasound Imaging Device That Is Inserted Into the Blood Vessels. It Has a Lot of Electronics and Is Tempting to Reprocess.**



# There Has Been a Design Change With a Detachable Shield

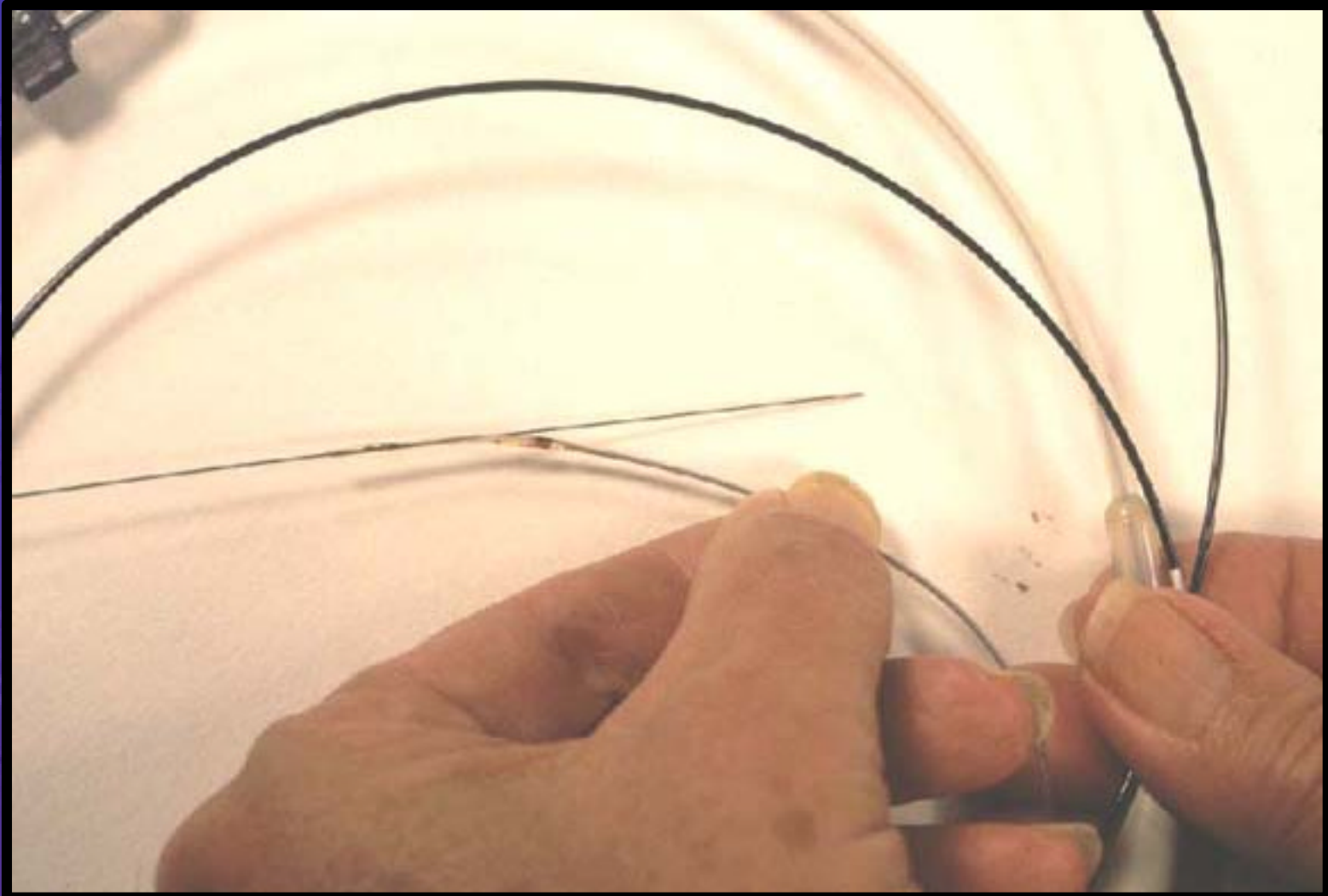


**In Both Designs, the Tip Goes Over a Guide Wire.  
This Guide Wire Channel Must Be Cleaned.**

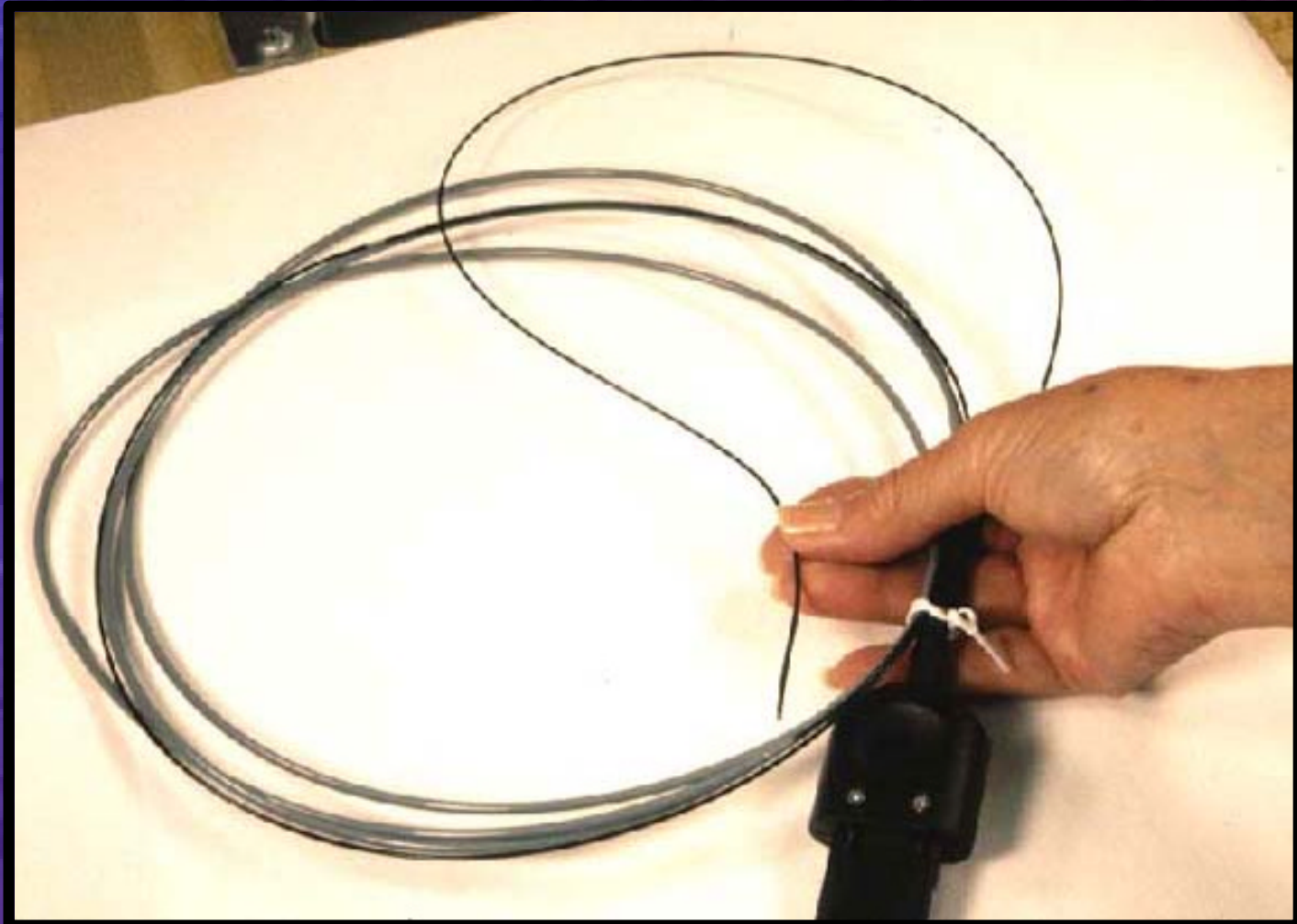




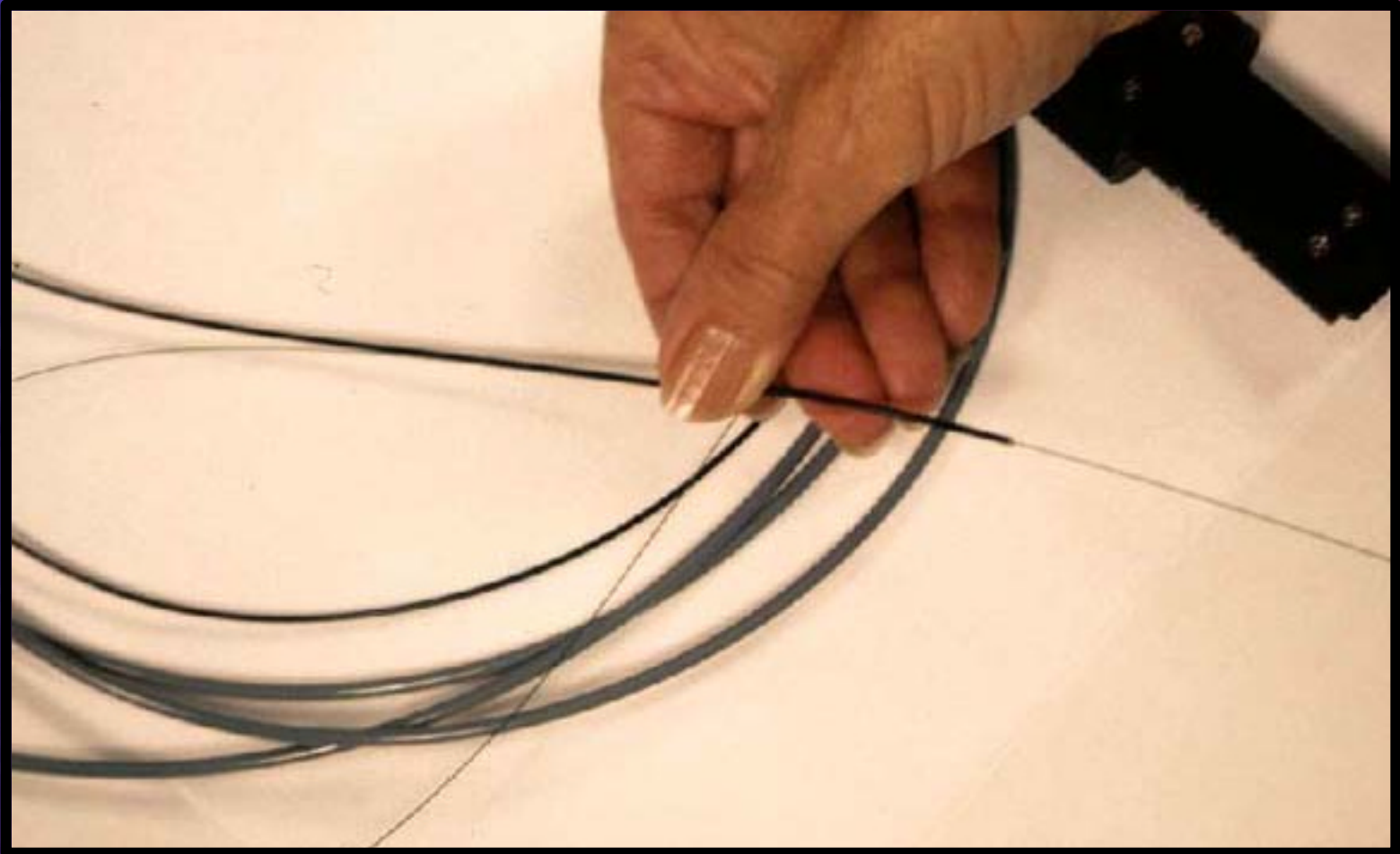
**This Shows the Short but Significant Channel**



**A Revascularization Device Is Tempting to Reprocess. It Too Goes Over a Guide Wire.**

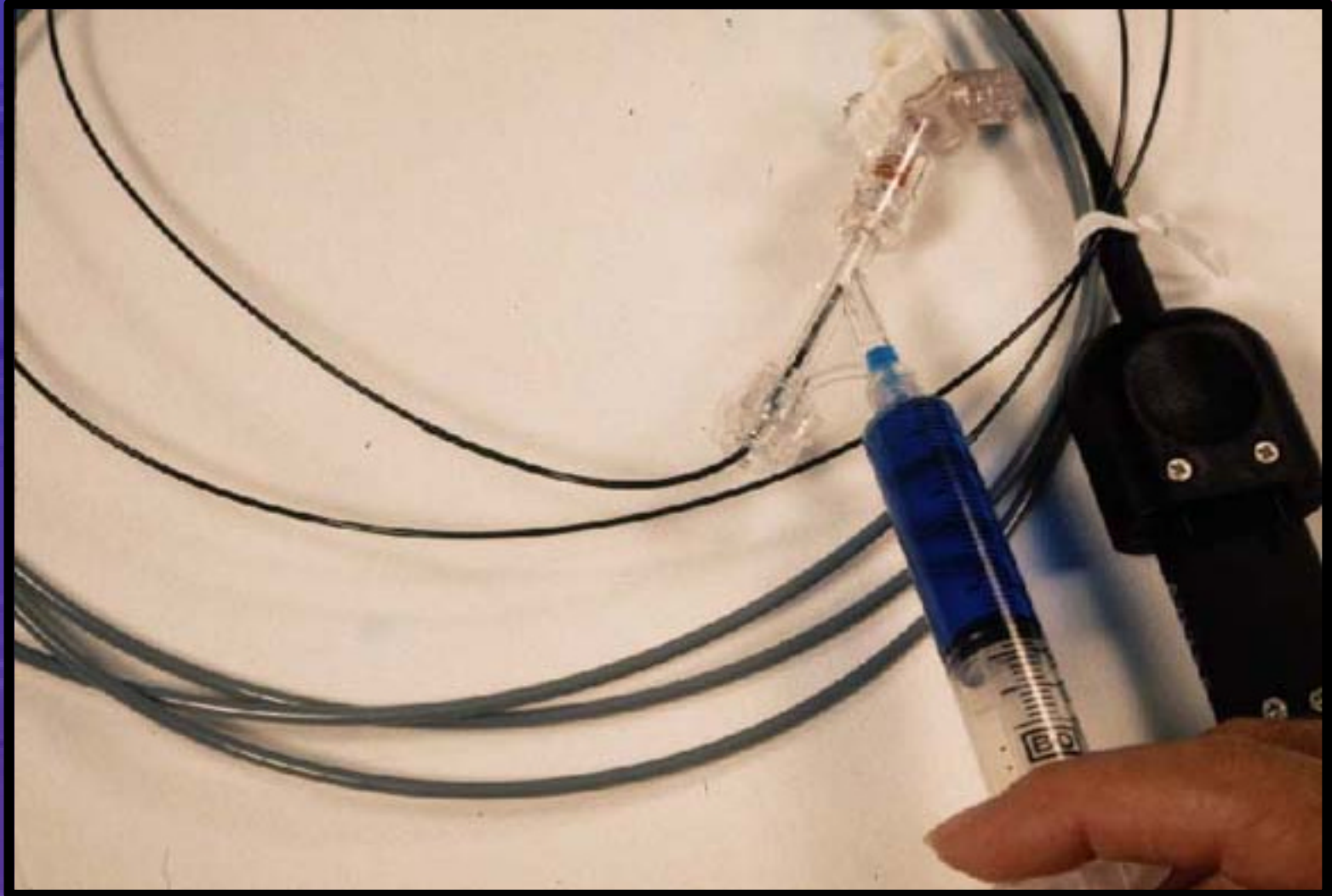


**Guide Wire Goes Into the Tip and Out the Shaft a Little Way up. This Lumen Needs to Be Cleaned.**

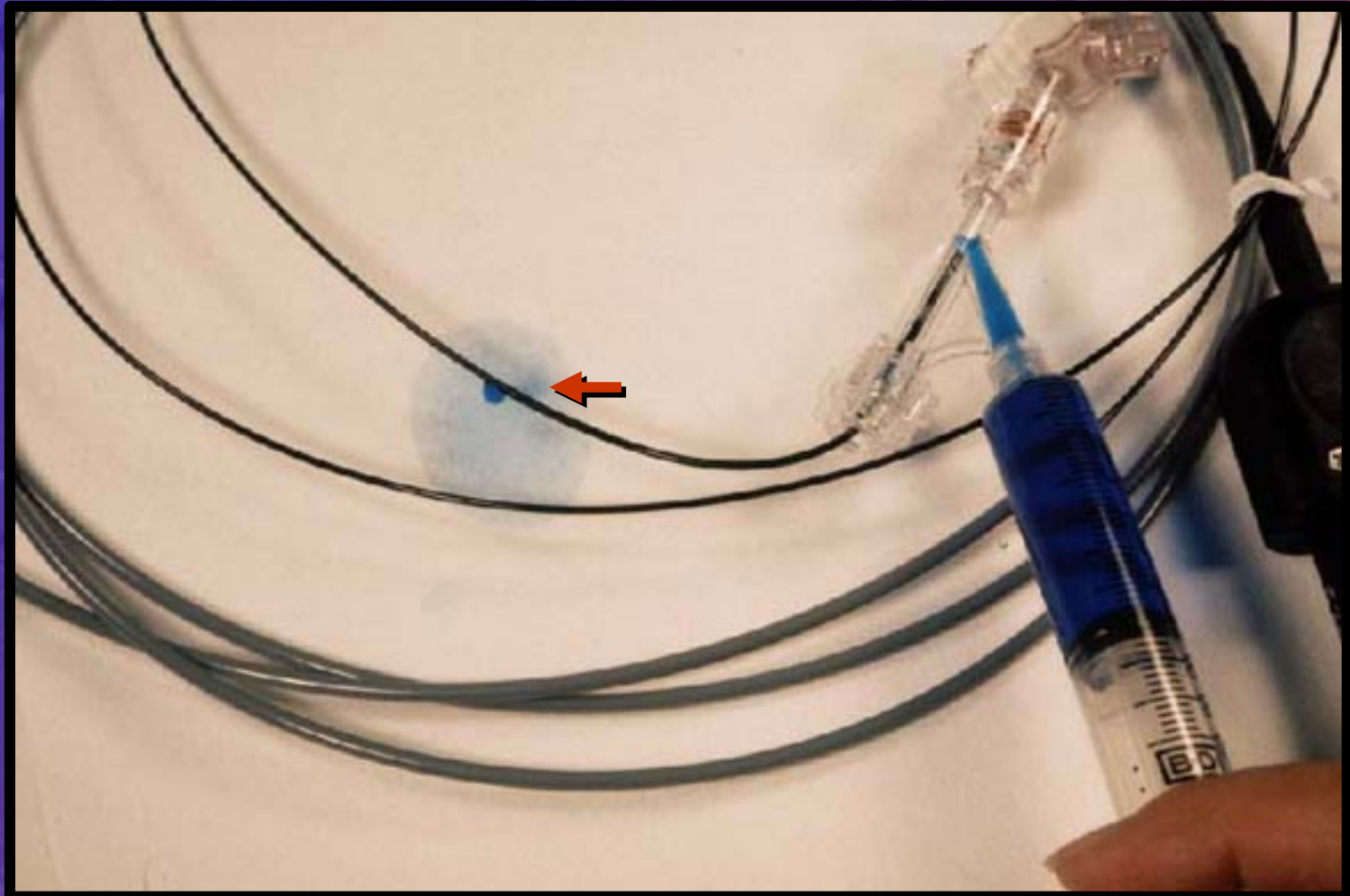




## Tuohy and Dye Could Be Used to Demonstrate the Lumen



**Dye Was Forced Into the Tip and Came Out  
End of the Lumen**



# **Other Catheters and Devices**

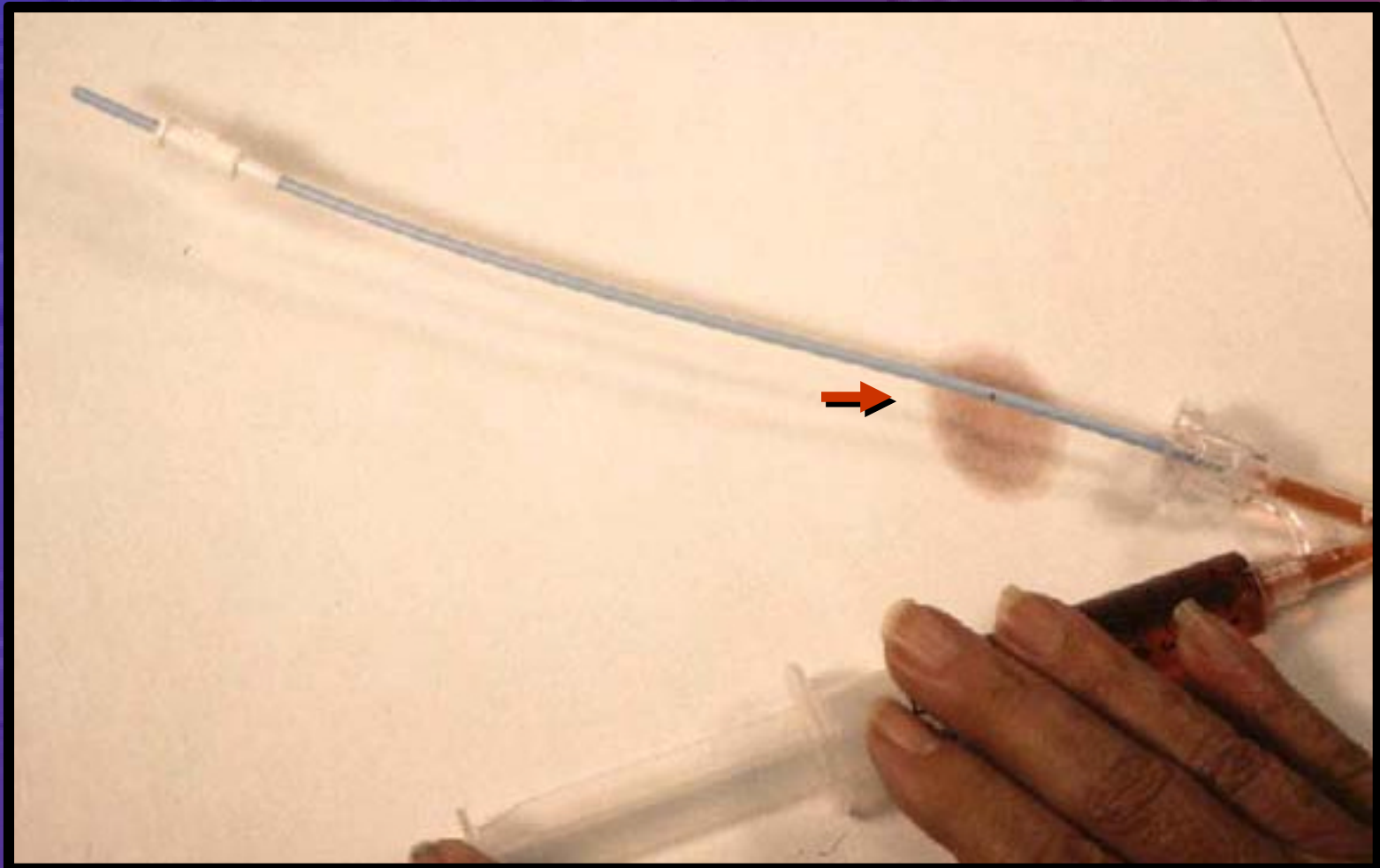
- **Some other devices seem robust and easy to clean**
  - **When examined the lumens are hard to clean since there are vent holes**
  - **Holes and lumens must be cleaned**



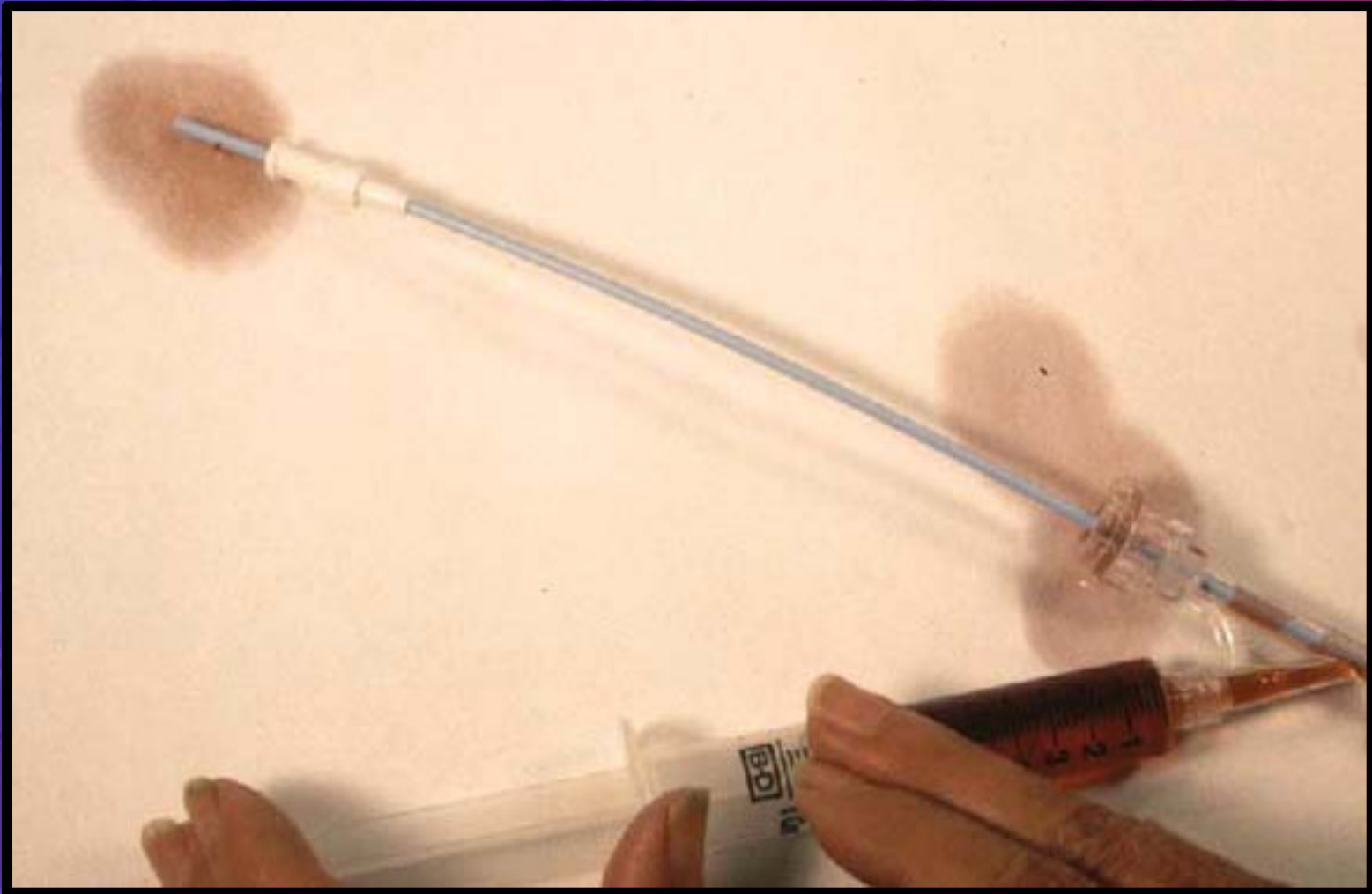
**Piece of a Hemostasis Device Which Is Unlikely  
to Be Reprocessed.  
However, It Points Out Some Difficulties.**



**A Tuohy Can Be Used to Identify Problems.  
There Are Various Holes in Some Shafts.**

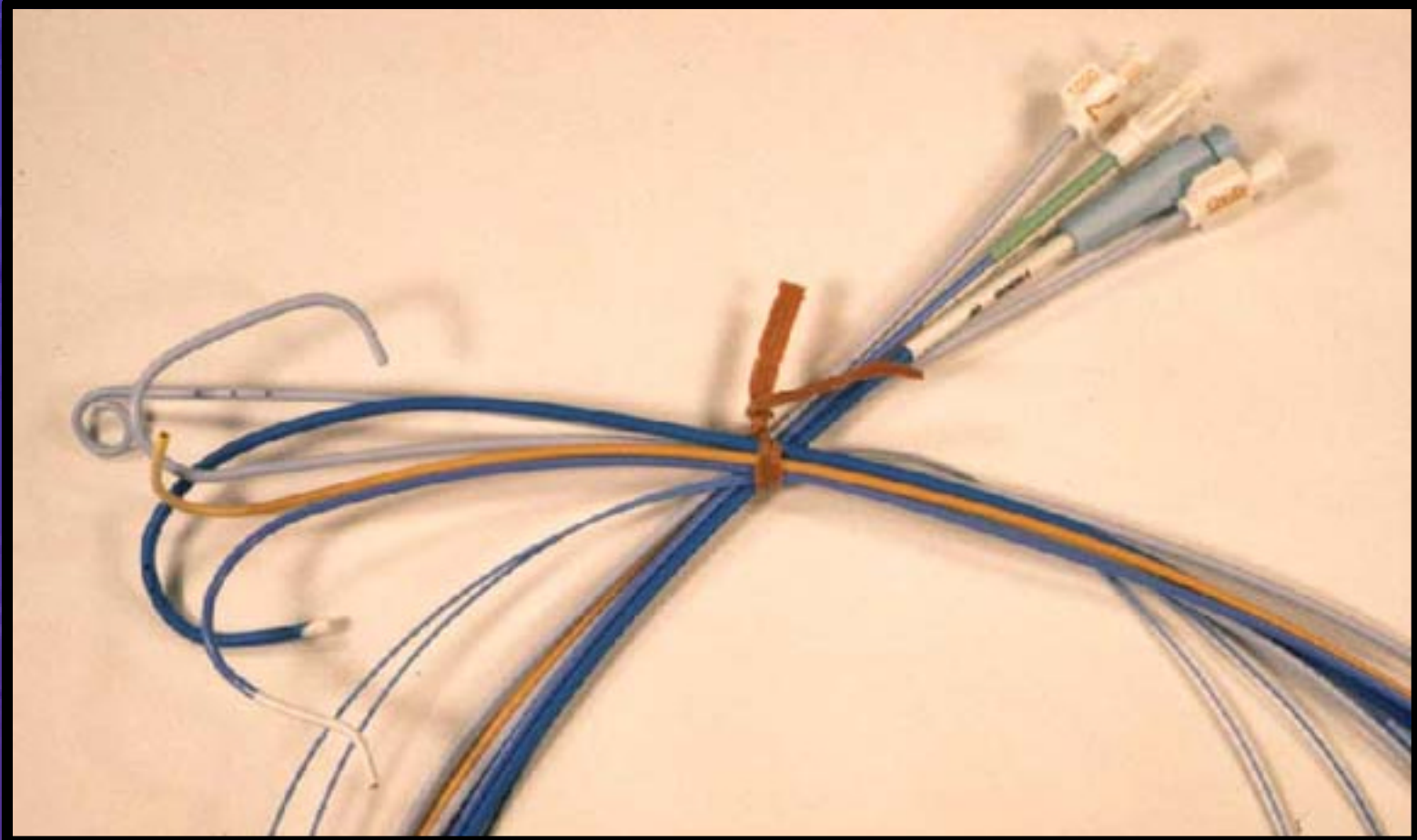


# Cover One Hole and Dye Comes Out Elsewhere

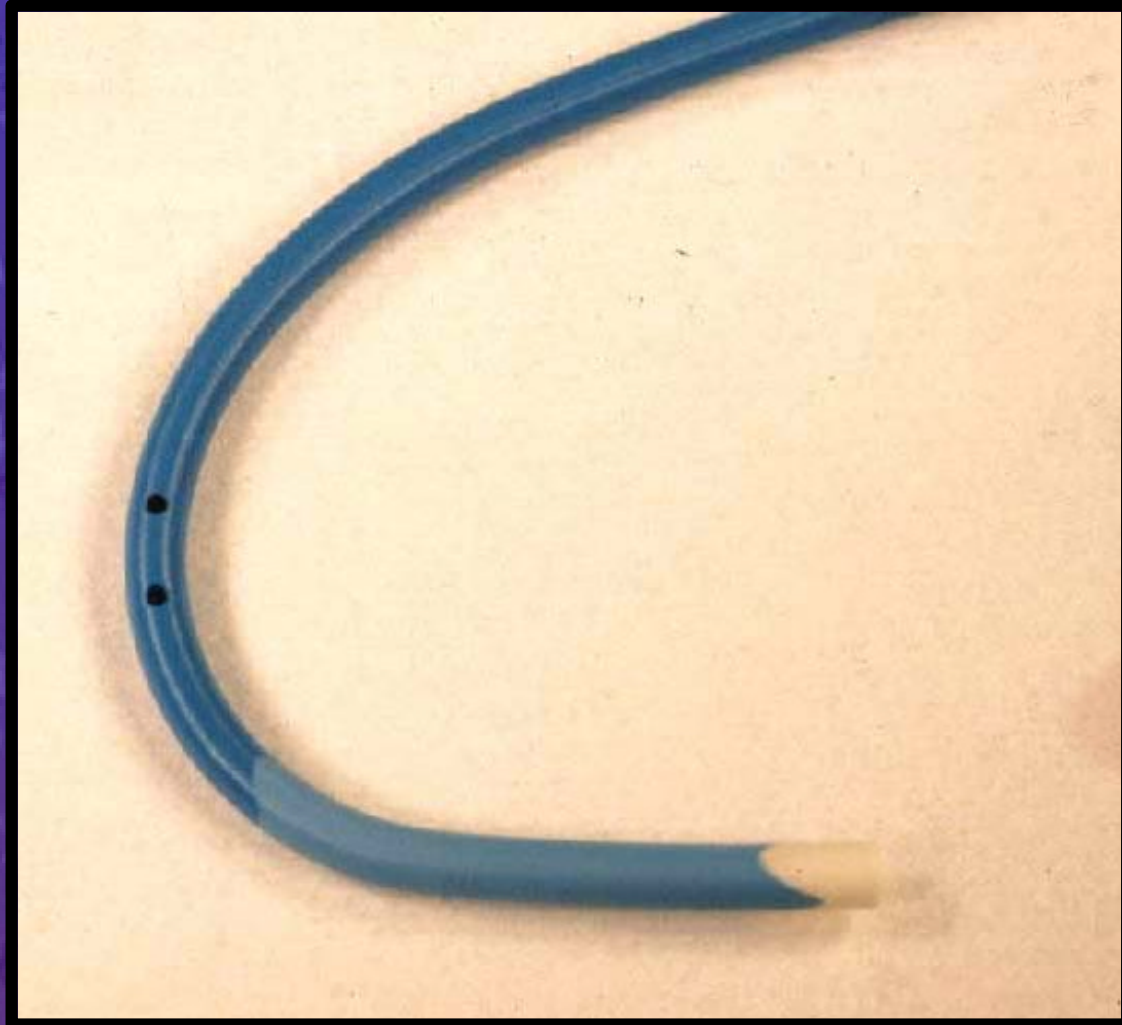




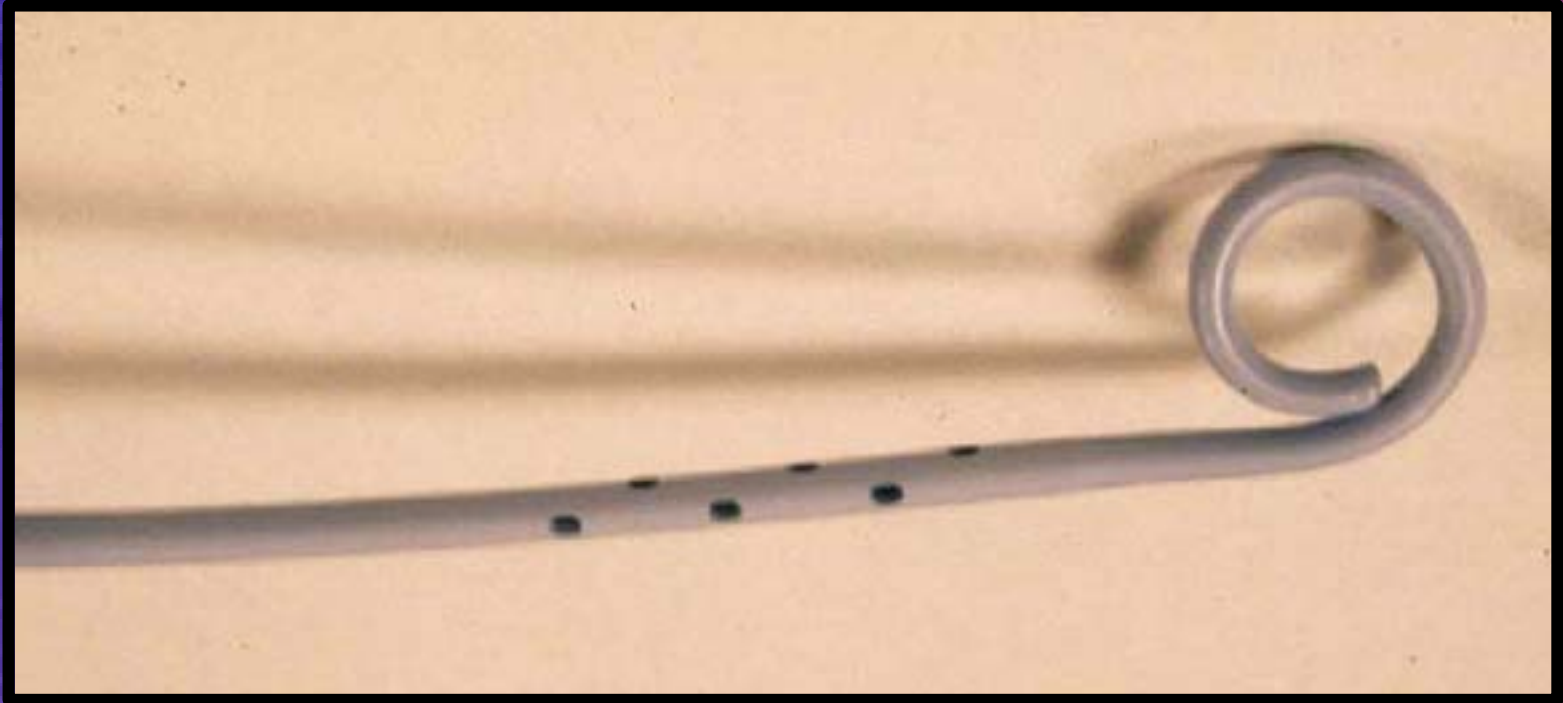
**There Are Many Shapes to Angiography and Guiding Catheters. The Shape Must Be Preserved and the Lumens and Holes Cleaned.**



# Guiding Catheter With the Vent Holes



# Pig Tail With Vent Holes





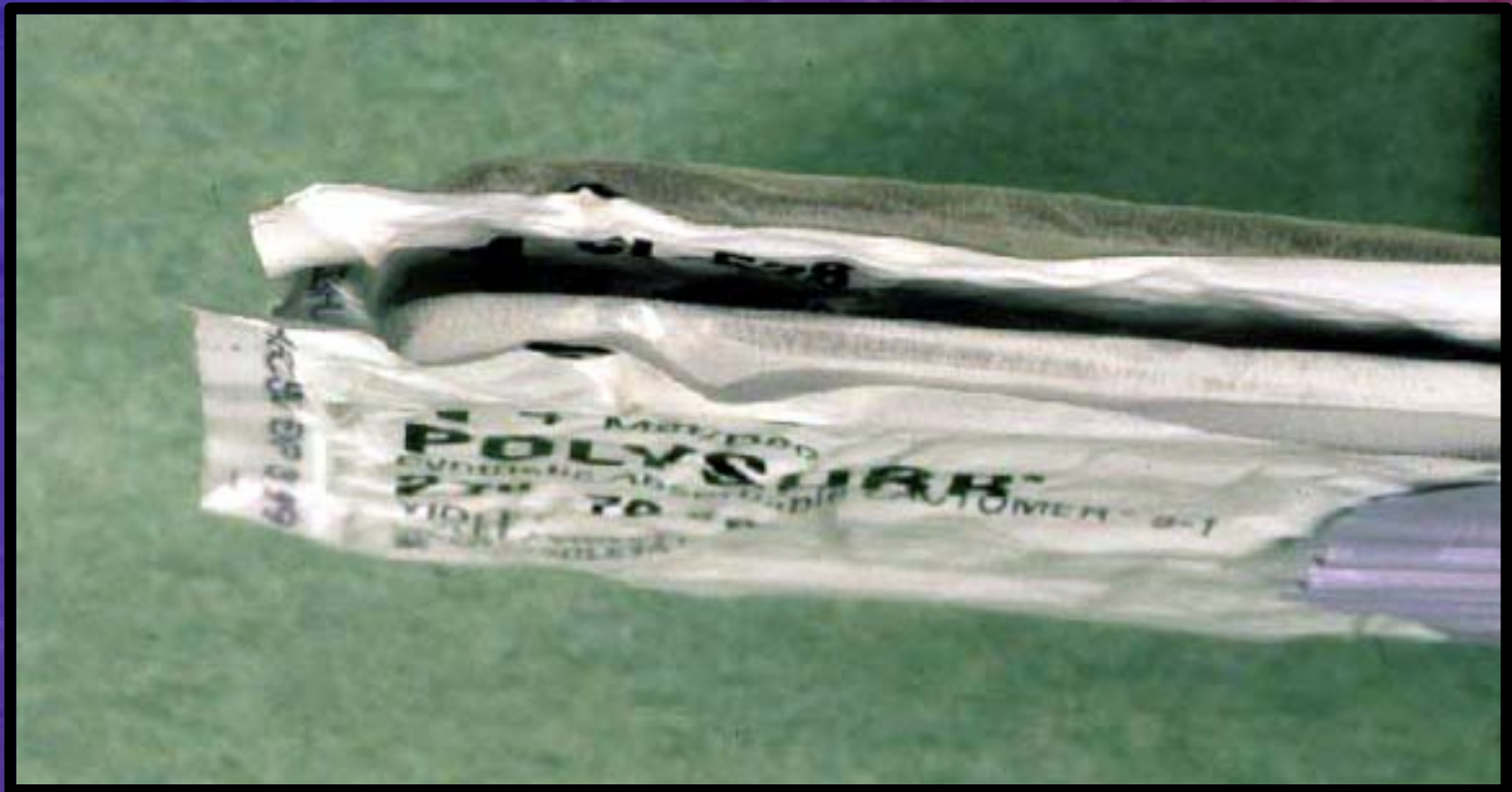
# Opened but Not Used

- Regulations will come later
  - Example of why there is concern
    - suture packs

**Suture Pack Resterilized Using Ethylene Oxide Gas. Note the Blister on Side Leading to Unsterile Contents.**



## Another Set of Suture Packs Resterilized With Damage to Package Integrity





# Bottom Line

- Know the devices well.
- Open lumens trap patient debris to be passed on to the next patient.
- Cleaning open lumens must be done carefully.
- Any device inserted over a guide wire has an open lumen and guide wire tracks blood, etc. into the lumen.

# Performance Issues

- **Electrical:** EP's, ablators, hot biopsy forceps, etc. must meet specifications and insulation must be intact.
- **Biopsy devices:** jaws must work, other extraction mechanisms must work.
- **Balloons:** lumen must be patent and the balloon size and shape meet specs.

# **Sterilization**

- **Final and critical step.**
- **Know materials: heat sensitive etc.**
- **Know recommended sterilization procedure for device: ETO on a radiation sterilized device may greatly increase residuals.**
- **Outgassing for 7-10 days may be needed.**



# Disinfection

- **Some non critical devices are high level disinfected rather than sterilized**
  - **Know the material compatibility**
  - **Remove residuals**
  - **Follow the SOP's**

# Final Comments

- Reprocessing SUD's correctly is not a trivial task.
- It is easy to do it wrong.
- It is hard to do it right.
- That is why the practice needs regulating.